THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:			
	Dov Malonek et al.	:	Examiner: G.R. Evanisko
Serial No.:	09/849,637	:	Group Art Unit: 3762
Filed:	May 4, 2001	:	Confirmation No.: 6911
For:	**Multi-Electrode Lead**		

January 31, 2007

SUPPLEMENTAL DECLARATION UNDER 37 C.F.R. §1.132

I, Shawn Moaddeb, hereby declare and say, that:

Background and Experience

1. I have a Bachelor of Science degree in Physics and Applied Engineering and a Masters of Science degree in Physics. Both degrees were received from Pittsburg State University.

2. I have over twenty-five years experience in the medical device industry including managing and resolving programs and launching new products.

3. I have applied for over forty patents in the medical device area, including improvements in leads for pacemakers or defibrillators.

4. I am currently on the Board of Directors of Oncogenics, Inc., a company involved in developing cancer diagnostics and products.

5. I am currently on the Board of Directors of Ellipse Technologies, Inc., a company focused on non-invasive therapy for obesity and GERD.

6. I am currently on the Board of Directors of MiCardia, Corp., a company focused on non-invasive simultaneous imaging and therapy based on external activation. At MiCardia, I have been responsible for all activities related to the development of next generation heart remodeling technologies. I have filed twenty-two patent applications in this area.

7. I spent ten years as an engineer and program manager specializing in medical device leads research and development.

8. A summary of my experience is attached hereto as Exhibit A.

9. I have been engaged by Impulse Dynamics N.V., the assignee of U.S. patent application Serial No. 09/849,637, to provide this Declaration. I am not, and have never been, an employee of Impulse Dynamics N.V., and I do not have any interest or relationship with Impulse Dynamics N.V. However, for the purpose of full disclosure, I should mention that I used to provide consultation services to one company and am now providing consultation services to a second company, and that I recently became aware that an indirect shareholder of both of said companies also holds an interest in Impulse Dynamics N.V.

The Application and Rejection

10. I have read and am familiar with the text of U.S. patent application Serial No. 09/849,637, filed May 4, 2001 (the "Application"), and the portion of the prosecution history of the Application relating to the rejection for lack of enablement.

11. I understand that the U.S. Patent and Trademark Office Examiner examining the Application has taken the position that the Application does not disclose how to make a unitary/signal electrode having a capacitance greater than 300 microfarads and less than 3000 microfarads, in combination with other elements in the claims, and that one skilled in the art could not practice/make the invention without undue experimentation to arrive at an electrode with a capacitance of 300 to 3000 microfarads.

12. As someone with experience in the field of creating leads and electrodes for modifying the activity of at least a portion of a tissue of human cardiac muscle, it is my opinion that one of ordinary skill in this art could read the Application and be able to produce an electrode having a capacitance greater than 300 microfarads and less than 3000 microfarads and that the electrode having a capacitance greater than 300 microfarads and less than 3000 microfarads could be produced without undue experimentation.

Background Technology

13. In general, the capacitance of a capacitor depends on three factors:

(i) The area of the plates;

(ii) The distance between the plates; and

(iii) The dielectric constant of the material between the plates.

14. Plate area affects the value of capacitance in the same manner that the size of a container affects the amount of water than can be held by the container. A capacitor with a larger plate area can store more charges than a capacitor with a smaller plate area. Simply stated, "the larger the plate area, the larger the capacitance."

15. The second factor affecting capacitance is the distance between the plates. Electrostatic lines of force are strongest when the charged particles that create them are close together. When the charged particles are moved further apart, the lines of force weaken, and the ability to store a charge decreases.

16. The third factor affecting capacitance is the dielectric constant of the insulating material between the plates of a capacitor. The various insulating materials used as the dielectric in a capacitor differ in their ability to respond to (pass) electrostatic lines of force. A dielectric material, or insulator, is rated as to its ability to respond to electrostatic lines of force in terms of a value called the dielectric constant. A dielectric material with a high dielectric constant is a better insulator than a dielectric material with a low dielectric constant.

17. The formula used to compute the value of capacitance is:

$$C = 0.2249 \frac{KA}{d}$$

where C = capacitance in picofarads

A = area of one plate, in square inches

d = distance between the plates, in inches

K = dielectric constant of the insulating material

0.2249 = a constant resulting for conversion from Metric to English units

18. One skilled in the art would appreciate that, in addition to what is set forth above, there is a known linear relationship between capacitance and both porous coating

thickness and physical morphology. Stated another way, those with ordinary skill in the art know that higher porosity and thicker material result in higher capacitance values.

19. At the time of the filing of the Application, typical pacemaker tip electrodes were in the range of from 4 to 8 mm^2 and a ring electrode was about 5 to 20 times larger.

20. TiN electrodes developed in the late 1980s used a reactive sputtering technique and achieved a high capacitance value by creating diamond-like morphology with a thickness of from about 10 to 30 microns.

21. Capacitance was additionally increased by providing a base metal from Pt/Ir covered with Pt/Ir particles in the range of from about 25 to 50 microns, and then the particle/base combination was coated with TiN. This effectively increased the surface area without increasing the physical geometric area.

22. Thus, one with ordinary skill in the art could easily coat electrodes to have a desired capacitance, such as from about 300 to about 3000 microfarads, simply by picking materials stated in the Application - such as TiN, IrO, carbon, etc., and using various techniques for deposition such as such as reactive sputtering, ion-plating, sintering, vacuum deposition, ion-implantation, electrochemical plating, etc., to create diamond like or other morphologies with different thicknesses. If TiN is used, the resultant thicknesses of porous TiN would typically be from about 10 to 30 microns.

23. There are known companies who provide such services, such as Wilson Greatbach and Heraeus, who will produce an optimized coating based on a customer's capacitance requirements.

24. There are also various known biocompatible materials that may be used for the coating.

25. One with ordinary skill in this art would be aware of other techniques and materials for producing the claimed lead and would be aware of numerous published articles and scientific abstracts describing the same. All this could be accomplished by one skilled in the art, without undue experimentation, after reading the Application.

26. For implantable electrode applications, it is desirable to minimize the electrical impedance at the electrode-tissue interface by increasing the intrinsic surface area of the electrode. In M. Schaldach, "Fractal Coated Leads: Advanced Surface Technology for Genuine Sensing and Pacing," Progress in Biomedical Research, 259-272, June 2000, Schaldach discusses in detail the selection criteria for implantable electrodes, based on work done in the 1990's (see, U.S. Patent No. 5,571,158, issued November 5, 1996, columns 2 to 4, a copy of which is attached as Exhibit B).

Teachings From Prior Art Patents

27. There are numerous teachings in the prior art regarding electrode preparation that were known to or available to one skilled in the art as of November 4, 1999, the filing date of the PCT patent application corresponding to the Application, such that one skilled in the art could produce an electrode with the desired capacitance and that that electrode could be produced without undue experimentation.

28. For example, U.S. Patent No. 4,602,637 to Elmqvist et al. ("Elmqvist"), issued July 29, 1986, discloses a heart pacemaker system in this art. A copy of Elmqvist is attached as Exhibit C.

29. Elmqvist describes a method for creating porous electrodes using materials with particle sizes, or a porosity, in a range of from about 2 to 100 microns to create a double layer capacitance in a range of from about 10 to 100 millifarads per square centimeter.

30. In Elmqvist, an electrode with a double layer capacitance of up to 0.1 F/cm^2 is achieved using such a porous coating. A glassy carbon may also be used as is discussed in German Published Patent Application No. 2613072 - referenced in Elmqvist. Such a capacitance is even higher than that claimed. Lesser capacitance values may be easily obtained by simply generating thinner, or less porous electrodes.

31. In U.S. Patent No. 4,603,704 to Mund et al. ("Mund"), issued August 5, 1986, Mund describes in column 1, background section, how to activate a surface to achieve higher capacitance. Furthermore, in column 3, third and fourth paragraphs, Mund teaches how to make high capacitance electrodes using sputtering, including sputtering parameters. A copy of Mund is attached as Exhibit D.

32. U.S. Patent No. 4,611,604 to Botvidsson et al. ("Botvidsson"), issued September 16, 1986, also discloses the provision of electrodes with a capacitance in the range of from about 10 to 100 millifarads per square centimeter and discloses using materials with porous coatings for ring and tip electrodes to increase capacitance to 0.1 F/cm^2. In Botvidsson, the particle sizes of the materials are between about 1 micron and about 100 microns. A copy of Botvidsson is attached as Exhibit E.

33. In U.S. Patent No. 4,762,136 to Baker ("Baker"), issued August 9, 1988, Baker teaches how to make low polarization/high capacitance electrodes made from iridium oxide. See, column 6, last paragraph, and column 7, first through third paragraphs. A copy of Baker is attached as Exhibit F.

34. In U.S. Patent No. 5,318,572 to Helland et al. ("Helland"), issued June 7, 1994, Helland describes porous coatings made from Pt-Ir spherical particles. Furthermore, in column 8, lines 43 to 68, and column 9, lines 1 to 40, Helland teaches how to include titanium nitride on top of the spherical Pt-Ir electrode to further increase capacitance and lower polarization. A copy of Helland is attached as Exhibit G.

35. I understand that the Examiner has made reference to U.S. Patent 5,824,016 to Ekwall ("Ekwall").

36. Ekwall is not relevant to indicate whether one with ordinary skill in the art would be able to produce an electrode with a capacitance of from greater than 300 to less than 3000 microfarads.

37. First of all, the disclosure of Ekwall discloses techniques for minimizing current leakage.

38. And second, the coating used in Ekwall is limited in capabilities as it relies on oxide formation. Oxide formation is not very effective due to its capacitance limitation. It is therefore understandable that the capacitance values shown in Ekwall are only in the range of 1 to 15 microfarads, which has nothing to do with whether one with ordinary skill in the art would be able to produce an electrode with a capacitance of from greater than 300 to less than 3000 microfarads.

39. Oxide formations are usually very thin without high surface area. To increase capacitance, a porous material used to increase surface area may be utilized as is shown in Elmqvist and Botvidsson.

Example

40. To demonstrate that one skilled in the art can prepare a lead according to the invention after reading the Application and without undue experimentation, I will now provide an example of how one with ordinary skill in this art would be able to produce an electrode with a capacitance of from greater than 300 to less than 3000 microfarads. It should be clear that other methods are known and available:

41. A 90%Pt/10%Ir metal may be used as a base.

42. If a tip electrode is being formed, a center of the base may be covered with from 50 to 70% porosity sintered 90%Pt/10%Ir particles ranging in size from about 40 to 60 microns. If a ring electrode is being formed, the porous 90%Pt/10%Ir need not be used.

43. A TiN layer is then applied in one or two steps: First, a dense TiN coating with a thickness of from about 0.5 to 2 microns may be applied over a ring or tip electrode. And second, for a tip electrode, a porous TiN coating with particle sizes and a thickness in the range of from about 10 to 30 microns may be applied over the dense coating.

44. The above steps create a diamond-like structure. Microporous structures like these yield very large effective surface area with increased capacitance and decreased polarization potential.

45. The TiN coating may be produced by evaporating high purity titanium using a DC or RF magnetron sputtering process. An electron beam in a presence of a reactive gas (such as pure nitrogen or in combination with argon) in a reduced pressure chamber will produce a fine, molecular scale vapor. The base material (electrode) will be placed in the sputtering chamber with the sputtering target made from Ti.

46. Typical sputtering parameters include: sputtering base pressure of 5.0×10^{-1} to 5.0×10^{-3} Pa and a total $Ar + N_2$ gas pressure of 3.0×10^{-1} to 4.0×10^{-4} Pa. A substrate to target distance may be about 0.05 meters. A substrate biased voltage of -200V may be used.

47. Porosity will increase as the sputter layer thickness increases in combination with specific surface morphology (diamond-like) as defined above. The

higher the surface porosity, the higher the capacitance. Porosity/capacitance is increased for the unitary/signal electrode.

48. Porosity increases and is established based on capacitance/polarization measurements. There is a direct relationship between the porosity and the capacitance value; the higher the porosity, the higher the capacitance.

49. In general, the larger surface area equals larger capacitance values. The way to increase the surface area is to do one or a combination of the following: increase the length, increase the thickness of the coating, and increase the porosity of the electrode. Electrode material is also a factor. Different materials have different capacitance at equal surface areas. Materials with high capacitance values coupled with larger length, thicker coating, with high porosity will be ideal.

50. A user may continuously monitor impedance, and, once impedance corresponding to the desired capacitance is reached, deposition may be terminated.

51. For the sintered porous Pt/Ir metal, metal powders can be mixed with special binders to form a slurry that can be applied to base metal substrates or used to form net shape components.

52. Subsequently, the metal base with the slurry material will be sintered in a sintering furnace at a temperature below the melting point of the metal but high enough to soften the metals to adhere to each other.

53. The above process has been used in medical devices for over twenty years.

54. A verification of the capacitance of the electrode may be performed by verifying the polarization of the electrode.

Conclusion

55. It is my opinion as an expert in the field of leads and electrodes, and as is shown above, that in November 1999 one skilled in the art with the Application before him or her would readily have been able to produce an electrode having a capacitance of from about 300 to about 3000 microfarads using techniques known in the art. Moreover, that art-skilled individual would have been able to produce that electrode without undue experimentation. This is clearly manifested in the example above, where I set forth the procedure according to which I or any other art-skilled person would be able to produce an electrode with a capacitance of from greater than 300 to less than 3000 microfarads using techniques known to one skilled in the art, particularly without undue experimentation.

I hereby declare that all statements made herein of my own knowledge are true, that all statements mode on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

January 31, 2007 Shawn Moaddeb

EXHIBIT A

Shawn Moaddeb
13712 Typee Way
Irvine, CA 92620
949-701-3545

SUMMARY

- Over 25 years experience with progressive responsibilities in the medical device industry, successfully managing and resolving technically challenging programs and launching new products.
- Co-founder and board member of three medical device companies.
- Experienced with setting up, raising money, and starting new businesses and ventures.
- Responsible for developing emerging markets. Worked with key opinion leaders to develop new products
- 42 patents received/submitted related to implantable pacemaker/defibrillator Leads, cardiology, biosensors, cancer therapy, bariatric surgery, GERD, and EP catheters.
- Received multiple R&D achievement awards.
- Published various scientific Abstracts at NASPE, ACC, & CARDIOSTIM for implantable pacing leads.
- Demonstrated leadership skills in cross-functional business team, providing both strategic and tactical direction.
- Excellent project management and organizational and financial management skills

EMPLOYMENT EXPERIENCE

2005 to present — **Oncogenics, Inc** — **Irvine, CA**
President & CEO
Co-founder and board member. Start-up early stage company. Technology is licensed from a world renowned cancer Institute. Several patents issued and pending. The company is developing cancer diagnostic, therapeutic planning, & assessment products. Conducted several proof of concept studies. Filed four new patent applications.

2005 to present — **Ellipse Technologies, Inc** — **Irvine, CA**
Co-Founder & COO
Company is focused on the development of non-invasive therapy for obesity and GERD. Spun-off of MiCardia Corp. Worked with key opinion leaders and collect information for the next generation device. Filed six new patent applications. The company is in process of raising $6MM to fund the development activities.

2004 to present — **MiCardia Corp** — **Irvine, CA**
Co-Founder & Vice President R&D
Member of executive management board. First employee of the company. Along with the other co-founder raised $4MM to start the company. New breakthrough dynamic remodeling technology based on non-invasive simultaneous imaging and therapy based external activation means. Responsible for all activities related to development of the next generation heart remodeling technologies for treatment of CHF and Mitral Valve Regurgitation. Filed twenty two patent applications related to CHF and mitral valve repair. Built an R&D team. Identified and moved to a new facility with clean room and machine shop capabilities. Established relationship with the key opinion leaders in this field. Formed scientific advisory board. Successfully completed proof of concept and conducted several animal studies. Developed new non-invasive electromagnetic activation technology to reshape and modify implant structure. Identified several new applications for this technology which resulted in formation of a new company.

1996 to 2004 **BIOSENSE – WEBSTER, A J&J COMPANY** **Diamond Bar, CA**
Group *Director – R&D*

Reporting to Vice-President of R&D. Managing R&D, process engineering, new Packaging development, & manufacturing engineering. Managing group of 30 professional staff with annual budget of $4MM

Member of the Biosense-Webster intellectual properties review committee.

Worked with new business development group identifying and assessing new opportunities with good business fit to BWI.

Responsible for bringing new products from R&D into manufacturing and transferring existing products to new facility in Juarez, Mexico.

Established new catheter assembly techniques to reduce labor, cost, and improving GP utilizing six sigma methodology.

Responsible for the next generation electrophysiology and cardiology product developments including: Percutaneous direct myocardial revascularization (Ho-YAG, Laser delivery system), myocardial injection catheter for gene/cell Delivery, fast mapping 3D electro-anatomical navigation, 8 mm tip with dual temperature sensors and irrigated thermocool catheters. Obtained CE-Mark approvals and initiated U.S. clinical trials for several new products.

1980 to 1996 **PACESETTER Inc. – A St. Jude Medical Company** **Sylmar, CA**
Advanced R&D *Program Manager – Leads Research*

Responsible for concept development of next generation pacemaker leads based on Hi-Impedance micro electrodes (micro-dot) with drug delivery capabilities. Evaluated new technologies for electrode surface modification such as porous structures, sputtering deposition, ion implantation and new coatings for drug delivery. Responsible for developing research project plan and schedule. Published scientific papers for NASPE, ACC and CARDIOSTIM medical symposia. Provided technical support to marketing and sales through meetings with physicians regarding new products and proposed technologies. Developed basic concepts, approaches, and performed initial experiments and feasibility trials. Supervised in-vivo, in-vitro studies, & proof of concept testing. Developed next generation hi-impedance TIN active fixation lead with drug delivery capabilities .

Sr. Development Engineer – Leads Development
Responsible for design, development, and transfer to production of Passive Plus and Passive Plus DX family of leads. The technology is based on low polarization micro-porous structure consist reactive sputtering of TiN over sintered pt/ir particles. Responsible for development of the first lead system with anti-inflammatory steroid delivery capabilities. Accomplished design & development tasks on new rate responsive pacemaker leads based on oxygen saturation optical sensor. Developed hermetic package for long-term implant based on glass/metal and metal/ceramic bonding. Conducted design of experiments to improve manufacturing processes. Developed expertise with the new families of polyurethanes, silicone rubber elastomers and methods of processing (bonding, molding). Enhanced knowledge of metal/metal and metal/polymer attachment techniques such as EB welding, Laser welding and surface modification. Developed familiarity with surface morphology analysis including Auger, ESCA, and SEM techniques.

1985 to 1986 **ADVANCED IN-VIVO DEVICES** **Los Angeles, CA**
Senior Design Engineer
Responsible for developing, designing and testing of various micro-sensors (oxygen saturation, Pressure) and micro-electrode catheters for long term implant.

1980 to 1981 **DATA GENERAL CORPORATION** **Sunnyvale, CA**
Development Engineer
Created modifications and improvements to advanced hard disk drives, developed test methodology and analyzed prototype anomalies.

TECHNICAL AWARDS / PATENTS / PUBLICATIONS

J&J R&D Achievement Award (1997, 1998)
J&J Patent Achievement Award (1998, 1999, 2000)
J&J Patent Achievement Award (2001,2002)
J&J Competitive Excellence Training
Certificate of Achievement in advanced pacemaker technology
Member of Physics Honor Society
Certificate in Project Management
Certificate for advance AutoCad training
Member of Biosense-Webster intellectual properties review committee
Patents submitted/received in following areas:

Devices to treat mitral valve regurgitation
Implantable devices to treat CHF
Non-invasive energy delivery system
Non-invasive HIFU activation system
Implantable devices for treatment of GERD and Obesity
Dynamic remodeling of GERD and Obesity implants.
Non-invasive activation technology to treat GERD and obesity.
Implantable magnetic devices to treat CHF and valve diseases.
-Hermetic packaging of implantable systems. (ACC, Cardiostim publications)
-Drug eluting defibrillator electrode
Rate responsive pacemaker lead based on Oxygen saturation
-Anti-inflammatory, anti-microbial pacemaker electrodes. (Cardiostim publications)
- Transvenous defibrillation/anti-tachy electrodes
-Micro sized pacing electrodes. (NASPE, Cardiostim publications)
-Active Fixation electrodes
-Low polarization defibrillator and pacemaker electrodes. (Cardiostim publications)
-Micro dose drug deliver systems for cardiac therapy
-Implantable defibrillation catheter with accelerometer
-Low impedance ceramic coating for pulse generators
-Radiopaque catheterization
-Unitary lead design
-Non-fluoroscopic lead placement
-Hi-impedance active fixation catheter for pacing
-Dual fixation leads
-Micro disk electrodes
-RF based myocardial revascularization catheter
-Fiberoptic direct revascularization laser catheter
-Drug delivery revascularization catheter
-RF ablation catheter with porous tip electrode
- Myocardial injection catheter for chemical ablation
-Low threshold Atrial defibrillator catheter
-Chemical and shockless defibrillator catheter
- Devices for capturing CTC and Circulating DNA in blood
-Device for continuous monitoring of CTC and CDNA in cancer patients.

EDUCATION

M.S. in Physics
Pittsburg State University, 1981–1982

B.S. in Physics / Applied Engineering
Pittsburg State University, 1977-1980

REFERENCES

Available upon request

EXHIBIT B

US005571158A

United States Patent [19]

Bolz et al.

[11] Patent Number: 5,571,158

[45] Date of Patent: Nov. 5, 1996

[54] STIMULATION ELECTRODE

[75] Inventors: Armin Bolz; Max Schaldach, both of Erlangen, Germany

[73] Assignee: Biotronik Mess- und Therapiegeraete GmbH & Co. Ingenieurbuero Berlin, Berlin, Germany

[21] Appl. No.: 193,042

[22] PCT Filed: Aug. 6, 1992

[86] PCT No.: PCT/DE92/00658

§ 371 Date: Jun. 23, 1994

§ 102(e) Date: Jun. 23, 1994

[87] PCT Pub. No.: WO93/02739

PCT Pub. Date: Feb. 18, 1993

[30] Foreign Application Priority Data

Aug. 6, 1991 [DE] Germany 41 26 362.6
Mar. 5, 1992 [DE] Germany 42 07 368.5

[51] Int. Cl.[6] A61N 1/04

[52] U.S. Cl. 607/121

[58] Field of Search 607/119–129, 128/642

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4,506,680	3/1985	Stokes	607/120
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3306668	7/1984	Germany .	
3306694	8/1984	Germany .	
3438221	4/1986	Germany .	
2613053	7/1987	Germany	
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OTHER PUBLICATIONS

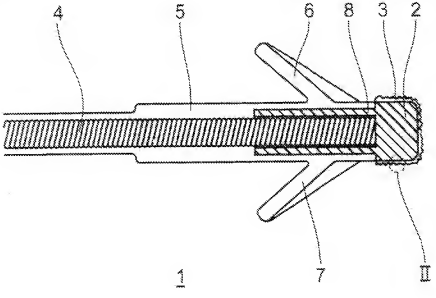
Biomedizinische Technik, vol. 34, No. 7/8, Aug. 1989, Berlin, Germany pp. 185–190, Schaldach "Titannitrid-–Herzschrittmacher–Elektroden".

Primary Examiner—William E. Kamm
Attorney, Agent, or Firm—Spencer & Frank

[57] ABSTRACT

A stimulation electrode having a porous surface coating whose active surface area is significantly greater than the surface area defined by the geometric shape of the electrode, wherein the surface coating comprises an inert material, i.e. a material having no or only a very slight oxidation tendency, wherein the material of the surface coating is formed from an inert element, an inert chemical compound and/or an inert alloy, and the active surface area, by virtue of its fractal-like geometry, is greater by a factor of at least one thousand than the surface area defined by the basic geometric shape of the electrode

8 Claims, 4 Drawing Sheets



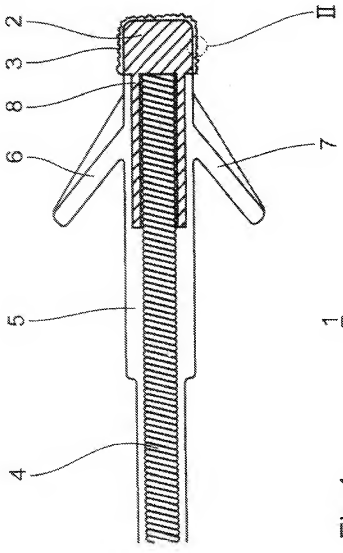


Fig.1

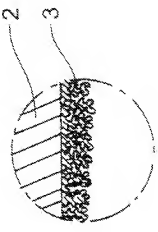
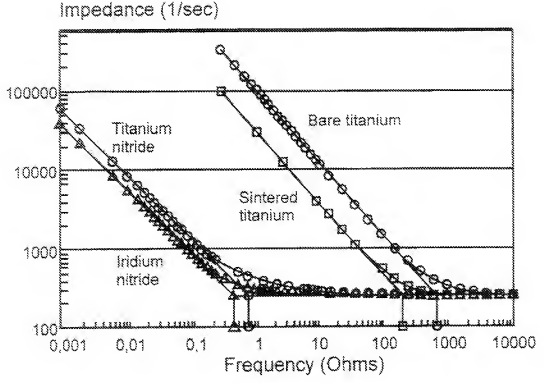


Fig.2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1000
100
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Bare titanium
Sintered titanium
Iridium nitride
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0,01
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1000
10000
Frequency (Ohms)

Fig.3

Fig.4a

Fig.4b

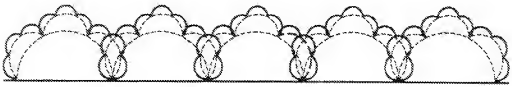

Fig.4c

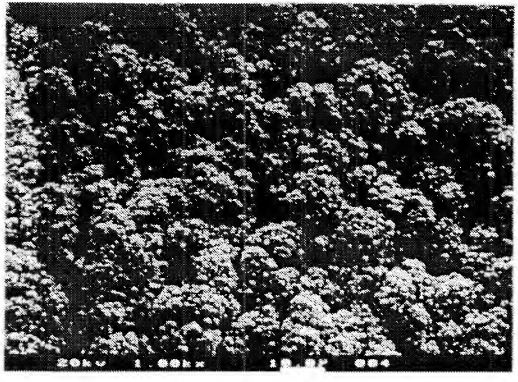

FIG. 5

STIMULATION ELECTRODE

CROSS-REFERENCE TO RELATED APPLICATION

This application is the U.S. national stage of PCT/DE92/00658 filed Aug. 6, 1992.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to a stimulation electrode having a porous surface coating whose active surface area is essentially larger than the surface area defined by the geometrical basic shape of the electrode.

2. Description of the Related Art

From an electrical standpoint, the phase limit between a solid body, that is, between the stimulation electrode of a pacemaker and an electrolyte, can be described in a simplified manner as a parallel switching of the phase limit capacity, i.e. the Helmholtz capacity C_H, and the Faraday resistance R_F, with which the line resistance R_L is connected in series. The impedance of the electrode system Z_{DL} is a function of the frequency ω of the applied voltage in accordance with the following equation:

$$Z_{DL} = R_L + \left(\frac{1}{R_F} + \omega^2 C_H^2 \right)^{-1/2} \quad (1)$$

A specified charge Q is required to stimulate the heart muscle, which charge can be calculated from the integral of the stimulation current I(t) over the pulse width T. Consequently, the impedance of the electrode system Z_{DL} can likewise be minimized when the quantity of energy required for stimulating the heart is minimized:

$$E = \int_0^T U(t) I(t) dt$$

Because the line resistance R_L is constant, the Faraday resistance R_F is defined with the following equation

$$R_F = \frac{R_0}{A} \quad (2)$$

where R_0 is a constant transfer resistance and A is the active surface area, and the Helmholtz capacity C_H is defined as follows:

$$C_H = \varepsilon \cdot \varepsilon_0 \frac{A}{d} \quad (3)$$

where ϵ is the dielectric constant of the added water dipoles, ε_0 is the dielectric constant of the vacuum and d is the thickness of the Helmholtz layer, the enlargement of the active surface area of the electrode according to (3) leads to an increase in the Helmholtz capacity C_H and, according to (2), to a reduction in the Faraday resistance R_F. According to (1), both then have as a consequence a reduction in the impedance Z_{DL} and in the required quantity of energy E. The active surface area A can be changed particularly by the enlargement in the electrode and/or by structuring of the electrode surface area.

Stimulation electrodes whose electrochemically active surfaces are enlarged by means of a porous layer composed of a carbide, nitride or carbon nitride, at least one of the metals including titanium, vanadium, zirconium, niobium, molybdenum, hafnium, tantalum or tungsten are already known from EP-A-0,117,972, EP-A-0,116,280 and EP-A-0,115,778.

A drawback of these known porous electrode coatings is that the overall capacity of the implanted electrodes decreases slowly over time, resulting in a corresponding increase in the required quantity of energy. Hence, the stimulation voltage must be selected relatively high in order to exceed the threshold response of the patient with the pulse energy over the long term. However, to emit the increased energy, an increase in the voltage of the pulses, which again results in an enlargement of the energy sources—and thus an enlargement in the housing—in implanted systems. The increase in pulse energy is accompanied by an increase in the polarization voltage, so that, after completed stimulation, the conventionally employed counterpulses must be correspondingly increased to prevent the effects of the polarization voltage on the input amplifier of the pacemaker.

It is an object of the invention to improve a stimulation electrode of the above-mentioned type in such a way that, on the one hand, the energy required for stimulation can also remain low in the long term and, on the other hand, that a reliable recognition of effectiveness is assured with simple measures.

SUMMARY OF THE INVENTION

This object is attained by providing a stimulation electrode having a porous surface coating whose active surface area is essentially larger than the surface area defined by the geometrical basic shape of the electrode, characterized in that the surface coating is composed of an inert material, i.e. a material with no or a very slight oxidation tendency, wherein the material of the surface coating is formed from an inert element, an inert chemical compound and/or an inert alloy, wherein, by virtue of the fractal-type spatial geometry, the active surface area is greater by a factor of at least one thousand times than the surface area defined by the geometric basic shape of the electrode.

The invention is based on the recognition that the materials of the known electrodes, and particularly titanium, vanadium, zirconium and niobium, exhibit a tendency toward partially extreme oxidation, and that, during contact with aqueous electrolytes, this strong oxidation tendency leads to the formation of a thin, insulating or semiconductive oxide layer that represents a capacity C_{ox} connected in series with the Helmholtz capacity C_H, and leads to a gradual reduction in the total capacity, and hence to a corresponding increase in the respective required stimulation energy. In anodic polarity, OH^- ions are drawn into the solid body, and there lead to an increase in the thickness of the oxide layer. The consequence of this is a further reduction in the phase limit capacity, and thus a further increase in the electrode impedance. The effect of the anodic pulses required for recognition of effectiveness in conventional charge integration methods is that the recognition of effectiveness cannot be performed with the known electrodes, or can only be performed with an increased quantity of energy.

Anodic polarity does not only occur in active counterpulses for recognition of effectiveness, however, but also in anodically polarized electrodes in multipolar pacemaker systems, or in impedance measurement in hearts. It can, moreover, be caused by overshootings of the stimulation pulses.

Hence, because of their relatively large surface area, conventionally coated, porous electrodes can initially achieve successful stimulation with low energy. It has been

recognized that the Helmholtz capacity is reduced by the oxidation tendency, leading to an increase in the electrode impedance. The influence of the electrode properties caused by this over the duration of implantation is therefore very serious, because the deterioration in the electrode properties has effects that in turn contribute to the additional unfavorable influence on the stimulation properties. Thus, a higher energy is necessary in a deteriorating electrode, so recognition of effectiveness also requires a counterpulse with a higher pulse energy, which in turn contributes to the deterioration of the electrode properties. Because the pulse energy and the counterpulses required for recognition of effectiveness are set at values that must be valid for the entire duration of implantation of the pacemaker, in the end the worsening of the operational conditions essentially is based on measures that should actually counteract the worsened operating conditions.

The biocompatible surface coating of the stimulation electrode of the invention, which exhibits long-time stability, is composed of a material whose oxidation tendency is very low, and is preferably applied in the electrode using vacuum technology and a substantially inert material, such as a nitride, carbide, carbon nitride or a pure element or specific alloy from the group that includes gold, silver, platinum, iridium or carbon. Due to the fractal spatial geometry of a surface layer applied in this manner, its active surface area is very large, so the quantity of energy required for stimulation can be kept small.

The afterpotential of a stimulation electrode made of titanium and having a sputtered iridium layer produced by reactive cathodic sputtering is up to six times (from approx. 600 to approx. 100 mV) less than the afterpotential of a bare stimulation electrode made of titanium. Because of this significant reduction of the afterpotential, the recognition of the intracardiac EKG is not only possible in a conventional manner with an amplifier and a triggering apparatus, but an operative effectiveness recognition that requires no counterpulses can be used.

As a result of the reduction in required stimulation energy over the service life of the implant, otherwise necessary reserves can be omitted, and the operating time of the implant can be advantageously and decisively lengthened, or, as the case may be, the size of the housing can be reduced significantly.

A specific charge Q is required for successful stimulation. The necessary current also charges the Helmholtz capacity C_H; consequently, following stimulus, a voltage, the so-called afterpotential, can be measured via the condenser. Since the voltage falling at a condenser is inversely proportional to the capacity when the charge is constant, the afterpotential is also reduced by a high Helmholtz capacity C_H, which is achieved by the large active surface area of the stimulation electrode of the invention, and the temporal change in the afterpotential is reduced. Because the inert surface layer of the stimulation electrode of the invention has no or a very slight oxidation tendency, the electrode can be operated anodically—if nonetheless desired under certain conditions—without an oxide layer forming and/or its layer thickness d increasing, so the Helmholtz capacity C_H can constantly be maintained at a high value, the afterpotential caused by the electrode can be kept as low as desired, and reliable effectiveness recognition thus assures optimization of the stimulation procedure.

The properties of the electrode of the invention are significantly improved with respect to prior electrodes by virtue of its fractal geometry, because the fractal-like, "cauliflower-like surface" creates porous structures that have a fine structure with a substantially increased surface area with respect to a surface that encloses the external geometry of the electrode. On the other hand, by means of the geometrical regions which, in connection with fractal geometry, have the rougher surface, areas are created that assure sufficient mechanical strength and serve as carriers for the regions having the finer geometric structure. It can therefore be seen that the active coating of the electrode has a geometric structure that becomes increasingly finer toward its surface. The size of the pores therefore decreases as they approach the surface. A structure of this type is comparable to a vascular system, which has in its peripheral regions a fine structure that opens into an increasingly coarse main vascular system.

Since the frequency spectrum of the intracardiac signals has a bandwidth of up to approximately 50 Hz, with a maximum of approximately 1 to 5 Hz, the transmission behavior, above all the considerable, low-frequency components of the frequency spectrum, can also be optimized if the Helmholtz capacity C_H is maximized.

Another advantageous feature of the stimulation electrode of the invention is that the signal amplitudes are increased during detection, because the detected voltage in all frequency ranges of the overall impedance of the electrode system Z_E and the phase limit impedance are based on the following equation (where U_{EKG} corresponds to the voltage of the intracardiac EKG initially present in the heart):

$$U_{det} \approx U_{EKG}\left(\frac{Z_E - Z_{DE}}{Z_E}\right) \qquad (4)$$

and the impedance of the electrode system Z_{DE} is minimized by the maximization of the Helmholtz capacity C_H.

Although the size of the active surface area could be changed by a simple enlargement of the electrode, it has been found that it is more advantageous to maximize the active surface area in relation to the surface area defined by the geometrical shape of the electrode, since a linear enlargement also only has as a consequence a surface area-proportional increase by approximation of the charge Q required for stimulation, and therefore does not represent a solution. This observation is clarified by the different influence range of the stimulation electrodes; more eloquently, a constant charge density would be required for heart muscle stimulation.

By virtue of their fractal geometry, the surface coatings of the invention, made of the above-named materials, and particularly of iridium nitride IrN, which are applied to conventional electrodes with the aid of modern vacuum-coating methods such as sputtering or ion-plating, assure a factor of 1000 and more in surface area enlargements. In fractal geometry, a number of an element is found repeated, but reduced, on larger elements having nearly the same shape. This assignment of shape can—at least approximately—be achieved with methods of thin-layer technology by setting the method parameters. The electrode of the invention also has surprisingly low stimulation threshold values over the long term.

With the option of utilizing anodic operation, the electrode can also be used advantageously in modes of operation in which this polarity is necessary for function, for example in bi- or multipolar electrodes or intracardiac impedance measurement.

The electrode of the invention is also suited in a preferable manner for neural stimulation, and generally for those types of stimulation purposes that are not dependent on high field strengths, but on low impedance and consequently large

tional charge or current densities adjacent to the organ to be stimulated or the affected neural pathways, respectively.

BRIEF DESCRIPTION OF THE DRAWINGS

Advantages of the invention are disclosed in the dependent claims and described in detail below, together with the description of the preferred embodiment of the invention, by way of the drawing figures. Shown are in:

FIG. 1 a schematic representation of an embodiment of a stimulation electrode of the invention in side view,

FIG. 2 an enlarged representation of detail II of FIG. 1 in section,

FIG. 3 a diagram for comparing the impedance of the embodiment of the electrode in accordance with the invention with that of prior electrodes of corresponding, identical geometrical dimensions,

FIG. 4 a representation of fractal surface geometry of the electrode in accordance with the invention, in which FIG. 4a shows a coating with a basic geometrical shape, FIG. 4b shows the basic geometrical shape scaled-down and superposed onto a larger basic geometrical shape, and FIG. 4c shows the basic geometrical shape scaled-down and superposed onto a larger basic geometrical shape as in FIG. 4b and superposed onto a still larger basic geometrical shape, and

FIG. 5 a section of the surface of the electrode in accordance with the invention in an enlarged representation.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The stimulation electrode 1 shown in a schematic side view in FIG. 1 is a unipolar, buried electrode whose head has a cylindrical base body 2 of titanium. In accordance with the invention, the cylindrical base body 2 has a surface coating 3 composed of an inert material, iridium nitride (IrN), and is applied to the cylindrical base body 2 of the titanium electrode by means of cathode sputtering. The electrode has a coiled, electrically-conductive lead 4 that is provided with an electrically insulating casing 5 of silicon. In the drawing, this silicon casing is illustrated as being transparent. Integral to the silicon casing are two backward-oriented, flexible fastening elements 6 and 7, which serve to anchor the electrode in the heart by keeping the surface of the base body in contact with the inside surface of the heart.

The base body 2 is pushed over the lead 4 by means of a hollow, cylindrical joined-on piece 8 and secured there; this joined-on piece is shown in section in the drawing.

FIG. 2 shows a section (detail II in FIG. 1) of the active surface on an enlarged scale. As can be seen from the representation, a significant enlargement of the active surface area is attained by means of the fractal, spatial geometry (not enlarged to scale) of the coating 3, which has grown in the manner of a stem in the macroscopic range. The achieved surface area enlargement is in a range of over 1000.

It can be seen from FIG. 3, which illustrates a comparison of the courses of the impedances of stimulation electrodes with different surface coatings, that an electrode coated with iridium nitride exhibits the lowest phase-limit impedance in comparison with the prior electrode surface coating materials titanium and titanium nitride, particularly smaller in range, in the low-frequency range that is particularly significant for receiving signals received from the heart. The determined differences are therefore of particular significance with regard to their effects, because the amplitude of the received signal is in a quadratic relationship with the inner resistance of the signal source.

Other embodiments of pacemaker electrodes in which anodic operation is desired are not shown in detail in the drawings. They are distinguished by a decreased surface area with respect to comparable, known electrodes, because certain surface reserves that had to be provided in the known electrodes for the case of impedance enlargement can be omitted. In bi- or multipolar electrodes, annular regions are provided that are removed from and opposite the electrode head and are provided with separate, galvanic connections to the connection-side end. By means of this, either a bipolar stimulation or an intracardiac impedance measurement for determining heart activity can be effected.

In the case that the pacemaker housing is used, a region of the housing oriented toward the body surface is provided with the coating of the invention, while the remaining part of the housing is provided with an insulating casing preferably composed of silicon caoutchouc.

It can be seen from the representation in FIGS. 4a through c how the basic shape of a semicircular cross-section is superposed in FIG. 4a by a Geometric shape that is correspondingly reduced to scale. The scaled-down shaping elements are added to the surface of the next larger basic shape. The next stage, that of superposition, is shown in FIG. 4c. The simplified illustration in these figures serves solely to represent the basic geometric relationships. In practical production, the basic forms can be superposed over spatially further stages.

The electron-microscopically enlarged representation of FIG. 5 shows the surface of an electrode in accordance with the invention that exhibits a cauliflower-like exterior. The structure is irregularly shaped, but follows the outlined fractal laws. Because the structure becomes continuously finer toward the outside, a microscopic surface is attainable that is multiple times larger in terms of surface area than the associated macroscopic surface area.

The invention is not limited to the above-described, preferred embodiment. Rather, a number of variations is conceivable that makes use of the solution shown, even in fundamentally different types of embodiments.

What is claimed is:

1. A stimulation electrode, comprising:

an electrode base body which has a basic geometric shape and a surface area; and

a porous surface coating which is provided on at least a portion of the electrode base body, which is comprised of an inert material having a low oxidation tendency effective to render the material substantially inert and being selected from the group consisting of a element, a chemical compound, and an alloy, which is porous and has a fractal spatial geometry, and which has an active surface area which is greater by a factor of at least one thousand times than the surface area of the electrode base body.

2. The stimulation electrode as defined in claim 1, wherein the inert material is selected from the group consisting of (a) an element selected from the group consisting of gold, iridium, platinum and carbon, (b) a chemical compound which is one of a nitride, a carbide or a carbon nitride of an element selected from the group consisting of gold, iridium, platinum and carbon, and (c) an alloy of at least two elements selected from the group consisting of gold, iridium, platinum and carbon.

3. The stimulation electrode as defined in claim 2, wherein the porous surface coating is composed of iridium nitride.

4. The stimulation electrode as defined in claim 1, wherein the electrode base body is composed of titanium.

5. The stimulation electrode as defined in claim 1, further comprising means for connecting the stimulation electrode to an anode terminal, and wherein the porous surface coating has an active surface area which is effective for anodic operation of the stimulation electrode.

6. A bipolar stimulation system, comprising:

a reference electrode which is a stimulation electrode according to claim 1; and

means for connecting the reference electrode to a reference terminal.

7. A stimulation electrode, comprising:

an electrode base body which has a basic geometric shape and a surface area; and

a porous surface coating which is a thin film applied to the electrode by a thin-layer technology process, which is

provided on at least a portion of the electrode base body, which is comprised of an inert material having a low oxidation tendency effective to render the material substantially inert and being selected from the group consisting of a element, a chemical compound, and an alloy, which is porous and has a fractal spatial geometry, and which has an active surface area which is greater by a factor of at least one thousand times than the surface area of the electrode base body.

8. The stimulation electrode as defined in claim 7, wherein the thin film is a vacuum deposited thin film, and wherein the thin-layer technology process is a vacuum coating method selected from the group consisting of reactive cathodic sputtering and ion-plating.

* * * * *

EXHIBIT C

United States Patent [19]

Elmqvist et al.

[11] Patent Number: 4,602,637

[45] Date of Patent: Jul. 29, 1986

[54] HEART PACEMAKER SYSTEM

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[73] Assignee: Siemens Aktiengesellschaft, Berlin & Munich, Fed. Rep. of Germany

[21] Appl. No.: 569,979

[22] Filed: Jan. 11, 1984

[30] Foreign Application Priority Data

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[51] Int. Cl.[4] A61N 1/04

[52] U.S. Cl. ..... 128/419 P

[58] Field of Search ..... 128/419 P, 784–786

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Primary Examiner—William E. Kamm

Assistant Examiner—Mitchell J. Stein

Attorney, Agent, or Firm—Hill, Van Santen, Steadman & Simpson

[57] ABSTRACT

Provided in order to avoid or at least reduce the problems produced by the passive electrode of a heart pacemaker system is a layer having a high double layer capacitance at the phase boundary with the bodily fluid. Advantageous to that end is a porous layer comprised of a carbide, nitride or carbonitride of at least one of the metals titanium, vanadium, zirconium, niobium, molybdenum, hafnium, tantalum or tungsten. The layer can also be comprised of activated carbon with a microporous exposed surface. The layer is produced in the simplest manner by means of roughening the existing electrode surface at its active area.

10 Claims, 3 Drawing Figures

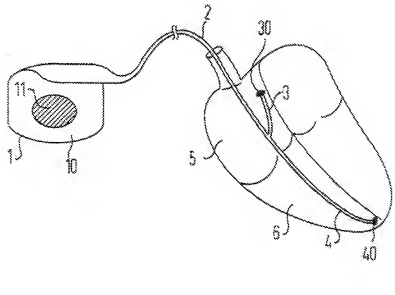


FIG. 1

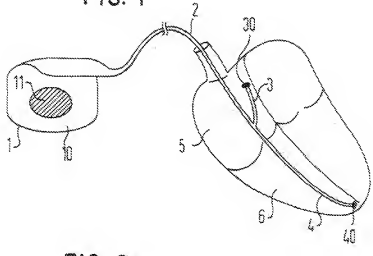


FIG. 2

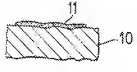
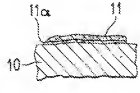


FIG. 3



HEART PACEMAKER SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

Reference is made to a copending application U.S. Ser. No. 569,832 filed Jan. 11, 1984 in the names of Konrad Mund, Helmut Preller and Friedrich Hoerauf, entitled "Electrode for Medical Applications" and to a copending application U.S. Ser. No. 569,980 filed Jan. 11, 1984 in the names of Lars Botvidson and Konrad Mund, entitled "Bipolar Electrode for Medical Applications".

BACKGROUND OF THE INVENTION

The invention relates to a heart pacemaker system comprising at least one active electrode and one passive electrode, in particular the heart pacemaker housing. Such heart pacemaker systems are employed, among other things for bifocal stimulation and have, for example, an active electrode which is introduced after the implantation of the heart pacemaker into the atrium of the heart and a further active electrode that is inserted into the ventricle of the heart. Essentially two demands are made of implantable stimulating electrodes which generally are comprised of an insulated conductor and an electrode head connected to said conductor and having the active region:

(1) The electrode material must be compatible with the body so that the formation of connective tissue layers having a thickness greater than one hundred microns (100 μm) is suppressed so that the stimulation threshold remains largely constant.

(2) A high double layer capacitance should develop at the phase boundary electrode/body fluid so that the polarization rise during the stimulation pulses (0.5 through 1 ms, 1 Hz, 10 mA, 10 mm^2) remains less than 0.1 V.

These demands are met to a particularly high degree by electrodes wherein the active region consists of glassy carbon (c German published application 2613072). A high double layer capacitance of up to 0.1 F/cm^2 is achieved due to an activation of the surface of the glassy carbon.

The only demand hitherto made of the passive electrode was that of compatibility with the body.

Given the said heart pacemaker system comprising two active electrodes and a shared passive electrode, problems can occur under certain conditions due to interactions between the electrodes. The cause thereof is a polarization rise at the passive electrode given stimulation with an active electrode. This polarization is slow to be dismantled and negatively influences the possibility of utilizing the other active electrode for detecting heart depolarizations during this time, since the polarization represents an increase of the electrochemical impedance of the system that makes the detection of the extremely small measurement currents considerably more difficult.

The functionability of the heart pacemaker system, further, can be negatively influenced by muscular convulsions. These muscle convulsions are generally based on the fact that the stimulation pulses not only stimulate the heart muscle but also stimulate stimulatable tissue in the proximity of the heart pacemaker housing which represents the passive electrode in the electrode system. The electrical voltage pulses associated with these muscle convulsions can simulate nonexistent heart activities under certain conditions. Previous attempts to eliminate this danger have been undertaken in that the heart pacemaker was surrounded by an insulating jacket. A hole through which the current can pass is situated in said jacket (SIEMENS-ELEMA brochure ME 372/5406.103, 1979). The heart pacemaker is then implanted such that the hole is situated at the side facing away from the stimulatable tissue. As a rule, the muscle convulsions stop.

In addition to these muscle convulsions, the problem also existed that the heart pacemaker could detect myopotentials of the skeletal musculature in the proximity of the heart pacemaker as depolarizations of the heart musculature. The danger of a negative influence on the heart pacemaker function as a result thereof also existed. This problem was also resolved by means of the insulating jacket and the proper placement of the heart pacemaker upon implantation.

This insulating jacket, however, also presents problems. First, the surface of the passive electrode is reduced, whereby the polarization effects increase and the efficacy of the stimulation pulses and the sensitivity of the heart pacemaker for detecting heart activities are reduced. On the other hand, problems regarding manufacture, hygiene and reliability arise due to this insulating jacket usually consisting of some kind or organic material.

SUMMARY OF THE INVENTION

It is therefore a principal object of the present invention to avoid or at least significantly reduce the problems produced in heart pacemaker systems of the type initially described due to the passive electrode and to increase the sensitivity of the electrode system at the same time.

This object is inventively achieved in that at least the active region of the passive electrode has a surface layer that provides a high double layer capacitance at the phase boundary with the bodily fluid. Thereby achieved, for example, is that the polarization rise upon stimulation is very slight. Given a bifocal system, therefore, stimulation can be carried out with one electrode and detection can be carried out with the other electrode with practically no loss of sensitivity.

It is also possible to leave the heart pacemaker housing conductive overall while yet serving as a passive electrode, i.e. to forego an insulating jacket. The surface hitherto left free of the insulation or a corresponding area is provided with the inventive surface layer and therefore exhibits a significantly lower electrochemical impedance relative to the surrounding tissue than does the remaining surface of the heart pacemaker housing. A voltage or, respectively, current division is thereby obtained. The area having the inventive surface layer will again be placed facing away from the stimulatable tissue or from tissues generating myopotentials when it is implanted.

It is particularly advantageous for the heart pacemaker system when, for example, the stimulation electrode and the passive electrode utilize the same material because material-associated potential differentials cannot occur in this case.

In an in vitro experiment, thus, a TiN stimulation electrode and two housing halves of the pacemaker fabricated of Ti were built into an electrolyte tank filled with 0.035M NaCl such that they simulated the heart pacemaker arrangement. Both housing halves were

separately contacted and the sub-currents, given load with galvano-static pulses (I = 10 mA, 1 ms), could be tracked via precision resistors. It turned out that the housing half facing the stimulation electrode is privileged at the beginning of the pulse and that the back housing half is more highly loaded after approximately 0.4 ms.

In the comparative experiment, the back housing part was provided with a six micron (6 μm) thick layer of porous TiN. It thereby turned out that the current is now preferentially carried by the back side after only 0.2 ms. Upon implantation, thus, this side should not contact any muscle tissue.

The inventive surface layer derives in a particularly simple fashion in that the conductive surface of the passive electrode—this is usually a matter, for example, of metallic materials such as platinum/iridium given heart pacemaker housings—is roughened in the active region. As a result of this roughening, the surface is quasi-enlarged by a multiple in comparison to a smooth surface layer, whereby a considerable increase of the double layer capacitance is already achieved. A further increase of the double layer capacitance is obtained in that the surface layer consists of activated carbon, in particular activated glassy carbon, as is already known for the electrode heads of the stimulation electrodes.

A surface layer that is particularly easy to manufacture and which is mechanically stable is formed by a porous layer consisting of a carbide, nitride or carbonitride of at least one of the metals titanium, vanadium, zirconium, niobium, molybdenum, hafnium, tantalum or tungsten.

The metals forming the carbides, nitrides and carbonitrides are all elements of the fourth through sixth sub-groups of the periodic system and thus include the so-called transition metals. Carbides MeC and nitrides MeN of the said type (Me=metal) are, for example, TiC, TiN, ZrC or TaN. The porous layer formed by such compounds has good conductivity and exhibits a thickness between one micron and one hundred microns (1 and 100 μm). Double layer capacitances that are of approximately the same magnitude as those of activated carbon thereby result. The manufacture of the layers, however, is considerably simpler. Tissue-compatible metals or metal alloys such as, for example, Elgiloy or, preferably, platinum and titanium serve as the carrier material for the layers.

In order to avoid the occurrence of mixed potentials, it can be provided in a further development of the invention that a tight nonporous layer which consists of the same material as the porous layer is situated between said porous layer and the carrier material. Under given conditions, it is thereby also possible to select a non-tissue-compatible material as the carrier material which is first surrounded with a tight nonporous layer of a tissue-compatible material that is then in turn coated with a porous layer of this same material, at least in the active region. The porous carbide, nitride or carbonitride layers are preferably applied to the carrier material serving as substrate by means of reactive ion plating, i.e. by means of physical vapor-deposition.

An exemplary embodiment of the inventive heart pacemaker system is described and explained in greater detail below with reference to a Figure of drawings; and other objects, features and advantages will be apparent from this detailed disclosure and from the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 schematically shows a system for bifocal stimulation of heart tissue constructed in accordance with the principles of the present invention.

FIG. 2 is a schematic representation (not to scale) of the porous and non-porous layers in FIG. 1.

FIG. 3 is a schematic representation of a further embodiment having an additional non-porous sealing layer.

DETAILED DESCRIPTION

The heart pacemaker system shown in FIG. 1 consists of the actual implantable heart pacemaker 1 having a closed housing 10 of, for example, titanium. An electrode line 2 for two stimulation electrodes 3 and 4 is shown connected to this heart pacemaker. The stimulation electrode 3 has an electrode head 30 which is provided for stimulating and sensing the heart activities in the left atrium 5 of a patient. The stimulation electrode 4 has an electrode head 40 which is correspondingly provided for the stimulation and detection of heart activities in the left ventricle 6.

What is essential to this heart pacemaker system is that the housing 10 of the heart pacemaker 1 is provided with an area 11 at one side thereof having a porous layer of, for example, titanium nitride. Two effects become simultaneously possible as a result of this coating, as shown in FIG. 2. It will be understood the layer 11 differs in porosity from the housing material 10 only microscopically, and FIG. 2 is, thus, greatly exaggerated. First, the double layer capacitance between the housing 10 and the surrounding tissue (not illustrated) is greatly increased, whereby polarization effects are avoided. Second, the possibility of disposing the housing during implantation derives such that the layer 11 faces away from stimulatable tissue or from muscle tissue generating myopotentials so that the electrical pulses deriving therefrom are essentially suppressed and do not have a negative influence on the function of the heart pacemaker system.

A further embodiment of the invention is shown in FIG. 3 wherein a tight non-porous layer 11a is disposed between the porous layer 11 and the housing carrier material 10. The non-porous layer 11a serves as a sealing layer, and consists of the same material as the porous layer 11. FIG. 3, as FIG. 2, is a schematic representation and is not to scale.

Elgiloy is a corrosion resistant alloy having the following components: cobalt, chromium, nickel, iron, molybdenum, manganese, carbon and beryllium.

A high double layer capacitance is a capacitance between the passive electrode at the active region and bodily fluid which permeates the active region which lies in the range from about ten millifarads per centimeter squared and about one hundred millifarads per centimeter squared when measured with a pulse repetition frequency of one hertz.

Titanium nitride-coated titanium sheets, for example, served for the determination of the electrochemical properties, having been investigated in a half cell arrangement with 0.15M NaCl as the electrolyte. A smooth platinum sheet served as cooperating electrode; an AgCl electrode was employed as the reference electrode. The electrodes were connected to a potentiostat and the potential values were converted and related to the potential of the reversible hydrogen electrode (H_2 electrode). The electrodes thereby set a potential of

$\phi/H_{2\ rev}=0.89$ V. (The specification $\phi/H_{2\ rev}$ denotes a potential referred to the reversible hydrogen electrode). Under potentio-dynamic load, with a voltage rate of change of ten millivolts per second (10 mV/s), one observed a constant current in the center of the interval $0 \leq \phi/H_{2\ rev} \leq 1$ V. Therefrom a double layer capacitance of 68 mF/cm^2 occurred at the beginning of the load, and this did not change over a load duration of eighty-eight hours (88 h). The investigations showed that no corrosion occurred up to a potential of 1.1 V; the electrodes are thus sufficiently stable.

The roughened surface layer at the active region **11** can be produced by roughening the exterior metallic surface of the wall of pacemaker housing **10** at active region **11** to provide at least twice the area of contact with bodily fluids as would be provided by a smooth metal surface of the housing **10** with a perimeter identical to that of the active region **11**. The roughened surface **11** may be permeated by bodily fluids to a depth between about one micrometer (one micron) and about one hundred micrometers.

The active region **11** may also be comprised of activated carbon with a microporous exposed surface permeated by bodily fluids to a depth between about one micrometer (one micron) and about one hundred micrometers.

The term "mixed potentials" refers to potentials produced because of the presence of different materials—i.e. material associated potentials.

We claim:

1. A heart pacemaker system comprising a heart pacemaker having a metallic heart pacemaker housing, and at least one active electrode, the heart pacemaker housing having a region serving as a passive electrode, said region having a surface layer forming relatively high double layer capacitance at the phase boundary between said region and the surrounding body fluid, and a remainder of the pacemaker housing of substantial area forming a double layer capacitance with said surrounding body fluid substantially less than that of said region, said remainder being formed by an external metallic surface of said pacemaker housing which is exposed to the body fluid.

2. A heart pacemaker system as claimed in claim **1** wherein said surface layer provides a double layer capacitance between about ten millifarads per centimeter squared and about one hundred millifarads per centimeter squared as measured at a pulse repetition frequency of one hertz.

3. A heart pacemaker system as claimed in claim **1**, wherein the surface layer is a roughened surface of limited extent of the metal wall forming the housing.

4. A heart pacemaker system as claimed in claim **1**, wherein the surface layer consists of activated carbon overlying a portion of said metal wall forming said housing.

5. A heart pacemaker system as claimed in claim **1**, wherein the surface layer is comprised of a porous layer of a material selected from the group consisting of a carbide, nitride or carbonitride of at least one of the metals titanium, vanadium, zirconium, niobium, molybdenum, hafnium, tantalum and tungsten, and wherein the metal wall forming the closed housing supports the surface layer and is comprised of a material selected from the group consisting of titanium and platinum.

6. A heart pacemaker system as claimed in claim **5**, wherein the surface layer has a layer thickness between two and one hundred microns.

7. A heart pacemaker system as claimed in claim **6**, further comprising a tight nonporous sealing layer of a material corresponding to the material of the porous layer disposed between the metal wall forming the housing and said porous layer.

8. A heart pacemaker system as claimed in claim **7**, wherein the tight nonporous sealing layer has a layer thickness between two and ten microns.

9. A heart pacemaker according to claim **1**, wherein said metallic pacemaker housing consists of titanium at its external surface except at said region, the surface layer being applied over the titanium of said housing coextensive with said region.

10. A heart pacemaker system according to claim **1**, wherein said metallic pacemaker housing consists of platinum at its external surface except at said region, the surface layer being applied over the platinum of said housing coextensive with said region.

* * * * *

EXHIBIT D

United States Patent [19]

Mund et al.

[11] Patent Number: 4,603,704

[45] Date of Patent: Aug. 5, 1986

[54] ELECTRODE FOR MEDICAL APPLICATIONS

[75] Inventors: Konrad Mund, Uttenreuth; Helmut Freller, Roethenbach; Friedrich Hoerauf, Nuremberg, all of Fed. Rep. of Germany

[73] Assignee: Siemens Aktiengesellschaft, Berlin & Munich, Fed. Rep. of Germany

[21] Appl. No.: 569,832

[22] Filed: Jan. 11, 1984

[30] Foreign Application Priority Data

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[51] Int. Cl.[4] A61N 1/04

[52] U.S. Cl. ..... 128/784; 128/419 P

[58] Field of Search ..... 128/419 P, 784–786

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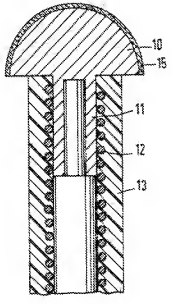
Primary Examiner—William E. Kamm

Attorney, Agent, or Firm—Hill, Van Santen, Steadman & Simpson

[57] ABSTRACT

In order to expand the availability of effective and usable electrodes for medical applications, an electrode is proposed which is comprised of an electrically conductive carrier material and of a porous layer in its active region which is composed of a carbide, nitride or carbonitride of one of the metals titanium, vanadium, zirconium, niobium, molybdenum, hafnium, tantalum or tungsten.

16 Claims, 2 Drawing Figures



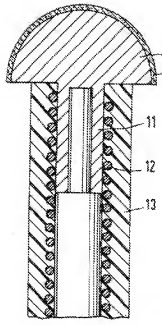


FIG 1

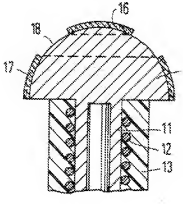


FIG 2

ELECTRODE FOR MEDICAL APPLICATIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

Reference is made pursuant to a copending application U.S. Ser. No. 569,980 filed Jan. 11, 1984 in the names of Lars Botvidsson and Konrad Mund, entitled "Bipolar Electrode for Medical Applications" and to a copending application U.S. Ser. No. 569,979 filed Jan. 11, 1984 in the names of Hakan Elmqvist and Konrad Mund, entitled "Heart Pacemaker System". German published application Nos. 33 00 694 and 33 00 672.

BACKGROUND OF THE INVENTION

The invention relates to an electrode for medical applications, particularly an implantable stimulation electrode.

Electrodes for medical applications are employed in the form of effectors and sensors. What is meant by effectors are electrodes with which a stimulating effect is exerted. Sensors are electrodes used for measuring. Examples of effectors are stimulation electrodes for heart pacemakers as well as electrodes for the stimulation of nerves and muscles. Particularly coming into consideration as sensors are microelectrodes for potential pick-up as well as EEG and ECG electrodes, i.e. electrodes for sensing brain and heart currents, respectively.

In most cases, implantable stimulation or stimulating electrodes, for example for heart pacemakers, consist of an electrode shank having an insulated cable lead and of an electrode head for the transmission of the stimulation pulses, i.e. the active or effective area of the electrode. Essentially two demands are made of such electrodes:

1. The electrode material must be compatible with the body, i.e. the formation of connective tissue layers should be very low if it is not suppressed altogether; in any case, the thickness should remain below one hundred microns (100 μm). The stimulation threshold, further, should remain largely constant.

2. A high double layer capacitance should form at the phase boundary electrode/bodily fluid, so that the polarization rise during the stimulation pulses (0.5 through 1 ms, 1 Hz, 10 mA, 10 mm²) remains less than 0.1 V.

The high double layer capacitance that is required has a beneficial effect in the case of stimulation electrodes and generally in the case of effectors as well because, as a result of the impressed current, only slight potential changes occur, electrochemical reactions with the bodily fluid are largely suppressed and the energy outlay is slight. In the case of sensors in which only a small measurement current flows, a high capacitance of the electrodes relaxes the demands that are made of the input impedance of amplifiers; noise is also reduced.

The demands cited above are particularly well met by electrodes wherein the electrode head, i.e. the active region in general, consists of glassy carbon. The high double layer capacitance of up to 0.1 F/cm² (ν=1 Hz) is achieved by means of an activation of the surface of the glassy carbon, whereby a thin, firmly adhering layer of activated carbon is obtained, i.e. a surface with a microporous structure.

Activated glassy carbon thus represents an electrode material having high capacitance that, beyond this, also exhibits good bodily compatibility and can therefore replace the metallic materials such as platinum/iridium for stimulation electrodes, platinum and tungsten for microelectrodes and silver/silver chloride for ECG electrodes which effect a degeneration of the adjacent tissue. Given glassy carbon, on the other hand, problems arise with respect to the mechanical processing (during manufacture) and the contacting, this in turn not being the case when metal electrodes are used.

SUMMARY OF THE INVENTION

A principal object of the invention is to avoid the problems regarding the electrode material hitherto occurring in electrodes for medical applications and to thus expand the availability of effective and usable electrodes.

This is inventively achieved in that the electrode is comprised of an electrically conductive carrier material and has a porous layer consisting of a carbide, a nitride or a carbonitride of at least one of the metals titanium, vanadium, zirconium, niobium, molybdenum, hafnium, tantalum or tungsten in its active region. The active region should thereby at least partially exhibit such a porous layer.

The metals forming the carbides, nitrides and carbonitrides are all elements of the fourth through sixth sub-group of the periodic system and are thus included among the so-called transition metals. TiC, TiN, ZrC, ZrN, TaC and TaN are, for example, carbides (MeC) and nitrides (MeN) of the said type (Me=metal). It is thereby essentially a matter of the stoichiometric compounds but deviations from the stoichiometric ratio can be present. The carbonitrides exhibit the composition MeC_xN_{1-x}, whereby x can assume a value between 0 and 1; for example, let the compound $TiC_{0.5}N_{0.5}$ be cited in this regard. In all instances, "mixed" compounds can also exist, i.e. Me can also stand for several metals in various proportions to each other; the carbide $(W,Ti)C$ is an example of such a compound. Beyond this, the said compounds can also be utilized in the form of mixtures.

Given the inventive electrode, the porous layer of metal carbide, metal nitride or metal carbonitride which has good electrical conductivity generally exhibits a thickness between one micron and one hundred microns (1 and 100 μm); the layer thickness preferably lies between five microns and fifty microns (5 and 50 μm). Double layer capacitances of 10 mF/cm² up to 100 mF/cm² thereby result. The inventive electrodes are comparable to electrodes of activated glassy carbon due to this high capacitance and the low polarization deriving therefrom as well as due to the good bodily compatibility which results in stability of the stimulation threshold. With respect to the contacting, the inventive electrodes exhibit advantages over glassy carbon electrodes since they consist of electrically conductive material.

The individual stimulation pulses in heart pacemakers last 0.5 through 1 ms. That means that the current must largely penetrate into the porous layer during this brief time in order to exploit the capacitance to the highest degree possible. This goal, however, can only be achieved when the ohmic resistance of the electrolyte in the pore system is sufficiently low, as is the case given the inventive electrode. Thereby characteristic is the product of volume-associated capacitance c, resistivity ρ of the electrolyte in the pores and the square of the thickness d of the porous layer. The limiting condition reads: $2\pi \cdot \nu \cdot c \cdot \rho \cdot d^2 < 1$.

The porous carbide, nitride or carbonitride layer is situated on an electrically conductive carrier material. This carrier material must be essentially blood and tissue compatible, i.e. compatible to the body. Metals and metal alloys such as Elgiloy and stainless steel (so-called VA steel) therefore come into consideration as the carrier material given the inventive electrode. Platinum and titanium are preferably employed; other precious metals can also be additionally employed. Beyond this, the carrier material can also consist, for example, of a synthetic coated with metal. Given the inventive electrode, at least the active region exhibits the thin, porous layer. Other (metallic) regions of the electrode can also be provided with such a layer under given conditions.

Given the inventive electrode, a dense nonporous sealing layer consisting of the same material as the porous layer can be situated between the carrier material and the thin, porous layer. With, for example, titanium as the electrode material, a dense nonporous titanium nitride layer can first be disposed thereon, followed by a porous titanium nitride layer. The formation of material-associated differential potentials can be prevented by means of the additional, dense nonporous layer. Beyond this, the demand that the carrier material must be physically compatible is thereby also eliminated. The thickness of the dense, i.e. nonporous sealing layer preferably amounts to between two and ten microns (2 and 10 μm).

The thin, porous layers are preferably applied to the carrier material such as titanium and platinum serving as substrate by means of reactive ion plating, i.e. by means of physical vapor deposition. With, for example, an electron beam evaporator, the metal for the porous layer is evaporated in an atmosphere containing nitrogen and/or methane (with, for example, argon present as an inert gas), being evaporated to this end from a supply of the metal forming the nitride, carbide or, respectively, carbonitride, and the corresponding metal compound, i.e. the carbide, nitride or carbonitride, is then deposited on the substrate as a thin layer. The N_2 or, respectively, CH_4 partial pressure thereby generally amounts to between $5 \cdot 10^{-3}$ and 10^{-1} mbar. The reactive ion plating can, however, also ensue with a magnetron sputter source, whereby the reaction gas pressures for N_2 or, respectively, CH_4 lie about one order of magnitude lower ($4 \cdot 10^{-4}$ through $1 \cdot 10^{-3}$ mbar).

Given the manufacture of an electrode wherein a corresponding, dense nonporous sealing layer is situated between the carrier material and the porous layer, one advantageously proceeds such that the N_2 and/or CH_4 partial pressure is slowly increased during the coating of the substrate, namely, for example, from a value between about $2 \cdot 10^{-3}$ and $8 \cdot 10^{-3}$ mbar to a value between $5 \cdot 10^{-3}$ and 10^{-1} mbar. Given such a procedure, namely, the dense i.e. nonporous sealing layer is first formed on the substrate and the corresponding, porous layer is formed thereafter. In addition to the N_2 or, respectively, CH_4 partial pressure, the formation of dense (nonporous) or, respectively, porous layers also depends, moreover, on the ion current of the gas discharge that is ignited between the substrate and the electron beam evaporator.

The inventive electrode is particularly suited for the following applications:

Stimulation electrodes

The pore system of the porous layer provides a high double layer capacitance which is aimed at, for example, use as stimulation electrodes of implantable heart pacemakers in order to keep the energy outlay low.

Microelectrodes

In the simplest case, these are thin wires having a diameter of less than fifty microns (50 μm) that are pointed. Such electrodes are advantageously essentially completely provided with a thin porous layer. The high double layer capacitance is then formed at the (active) electrode tip when immersed into the electrolyte, whereas the pores of the porous layer along the electrode shank, i.e. along the wire, represent a good bonding base for the insulation.

EEG and ECG electrodes

The high attainable capacitance is also here advantageous. But it is also significant that the porous layer is anchored to the carrier material in an abrasion-proof manner and the electrode—after appropriate cleaning—can thus be repeatedly employed.

Cooperating electrodes

It is advantageous when, for example, the stimulation and cooperating electrode consist of the same material because potential differences dependent on material cannot occur then.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a partial longitudinal sectional view for illustrating an electrode for medical applications with a porous layer having characteristics in accordance with the present invention; and

FIG. 2 is a view similar to FIG. 1, the electrode having a plurality of active regions each formed by a porous layer with a composition and other characteristics in accordance with the present invention.

DETAILED DESCRIPTION

FIG. 1 shows an electrode for medical applications, comprising so far as relevant an electrode head 10 having a stem 11 which is in electrical contact with a contacting helix 12, the helix 12 being covered by a suitable synthetic coating 13.

In accordance with the present invention, the electrode head serves as an electrically conductive carrier material in electrical connection with helix 12 and supports a porous layer 15 comprised of one or more compounds each consisting of a carbide, nitride or carbonitride of at least one of the metals titanium, vanadium, zirconium, niobium, molybdenum, hafnium, tantalum or tungsten. The porous layer 15 has a layer thickness between one micrometer (one micron) and one hundred micrometers, and preferably between about five micrometers and about fifty micrometers. By way of example the electrode head 10 and stem 11 may be of titanium or platinum, and the helix 12 may be of Elgiloy.

As explained in detail hereafter, in a further embodiment of the invention, the porous layer may be applied over a dense nonporous sealing layer of the same material as the porous layer. The dense nonporous sealing layer together with the synthetic coating 13 may completely cover the metallic material of head 10 and stem 11, so that thus metallic material is not exposed to bodily fluids when the electrode is implanted. The dense sealing layer may have a layer thickness between about two micrometers and about ten micrometers. Bodily fluids may penetrate the porous layer to a depth between

about one micrometer and about one hundred micrometers so as to be separated from the metallic carrier material only by the sealing layer; thus the separation between the bodily fluid and the metallic carrier material is in the range from about two micrometers to about ten micrometers.

FIG. 2 illustrates the same basic electrode configuration as FIG. 1, and corresponding reference numerals have been applied to the electrode head, electrode stem, the contacting helix and the synthetic coating. In FIG. 2 the electrode head 10 is shown as having spaced porous layers 16 and 17 which are separated from each other by region 18 without a porous layer. The porous layers 16 and 17 have the same composition and layer thickness as described for porous layer 15 of FIG. 1. The region or regions such as 18 may expose the metallic material of the electrode head 10 to bodily fluids where the electrode head is formed of a compatible material.

As described with reference to FIG. 1, the metallic carrier material of electrode head 10 of FIG. 2, in a further embodiment, may have a dense nonporous sealing layer which together with the synthetic coating 13 completely isolates the metallic material of electrode head 10 and stem 11 from bodily fluids when the electrode is implanted.

By way of example, the electrodes of FIGS. 1 and 2 may serve as implantable stimulation electrodes and provide a double layer capacitance measured with a pulse repetition rate of one hertz as explained herein, which lies in the range from about ten millifarads per centimeter squared to about one hundred millifarads per centimeter squared. The method of manufacture and detailed characteristics of the porous layers 15, 16 and 17 of FIGS. 1 and 2 may be as described in any of the following examples, and the electrode systems utilizing of the electrodes described in this section may provide the features and advantages as set forth herein in the section headed Summary of the Invention.

The invention shall be explained in greater detail with reference to examples.

In the investigations described below, electrodes whose porous layer exhibited a thickness of approximately thirty microns (30 μm) were respectively employed.

The structure of the porous layers depends on the manufacturing conditions. A needle-like structure was obtained given a N_2 pressure of one millibar wherein the needles have a diameter of about one-half micron (0.5 μm). The layer has a volume porosity of forty percent (40%).

Titanium nitride-coated titanium sheets, for example, served for the determination of the electrochemical properties, having been investigated in a half cell arrangement with 0.15 M NaCl as the electrolyte. A smooth platinum sheet served as cooperating electrode; an AgCl electrode was employed as the reference electrode. The electrodes were connected to a potentiostat and the potential values were converted and related to the potential of the reversible hydrogen electrode (H_2 electrode). The electrodes thereby set a potential of $\phi/H_{2\,rev}=0.89$ V. (The specification $\phi/H_{2\,rev}$ denotes a potential referred to the reverible hydrogen electrode.) Under potentio-dynamic load, with a voltage rate of change of ten millivolts per second (10 mV/s), one observed a constant current in the center of the interval $0 \leq \phi/H_{2\,rev} \leq 1$ V. Therefrom a double layer capacitance of 68 mF/cm² occurred at the beginning of the load, and this did not change over a load duration of eighty-eight hours (88 h). The investigations showed that no corrosion occurred up to a potential of 1.1 V; the electrodes are thus sufficiently stable.

In order to investigate the bodily compatibility of the electrodes, titanium sheets having a black, porous TiN layer as well as titanium sheets having a yellow, dense nonporous sealing TiN layer were implanted into the thigh muscle of cats (wafers having a diameter of 10 mm). After an implantation duration of 5 weeks, there were no differences with respect to the connective tissue growth between the various specimens, i.e. given passively implanted electrodes. Beyond this, the thickness of the connective tissue layer in all specimens amounted to less than sixty microns (60 μm), i.e. there is nearly ideal tissue compatibility.

Electrode heads in the form of hemispheres having a diameter of 2 mm were manufactured from Ti wire. These hemispheres were coated with porous titanium nitride, the electrode shank was contacted with an Elgiloy helix. (Elgiloy is a corrosion resistant stainless steel having the following components: Co, Cr, Ni, Fe, Mo, Mn, C and Be.) Given electrodes intended for implantation, moreover, the electrode shank is always coated with a suitable material such as a synthetic so that no problems with respect to the physical compatibility thereby derive. The double layer capacitance of such stimulation electrodes—which was identified potentiostatically from impedance measurements—derived at 21.5 mF/cm² in 0.15 M NaCl given $\nu=1$ Hz. The value could be increased to 48 mF/cm² given further specimens of stimulation electrodes. Because of the high porosity of the layers, however, this capacitance is available up to frequencies of 10 Hz. The capacitance decreases with increases of frequency and reaches a value of 8 mF/cm² at a frequency $\nu=100$ Hz. This drop is caused by the porous structure of the layer and the penetration depth of the current decreases with increasing frequency as a consequence of the electrolyte resistance. The capacitance measurements were conducted at an impedance test location, whereby a potentiostat was coupled to a frequency response analyzer. The imaginary component of the impedance was interpreted.

In in vitro experiments, stimulation electrodes were loaded together with a heart pacemaker at a voltage of 5 V, a pulse duration of 0.75 ms and an electrolyte temperature of 40° C. over a time span of 4,500 hours. A capacitance decrease of 20% was observed over the first 1,000 hours but the value of the capacitance then stabilized.

A capacitance of 10.5 mF/cm² (given $\nu=1$ Hz) was identified in the animal testing (implantation of the stimulation electrode in the thigh muscle of cats). Conditioned by the body fluid, this value lies approximately 50% lower than the value of the in vitro measurements (NaCl). But what is thereby significant is that the capacitance values did not change even after an implantation duration of 42 days. A thin connective tissue layer having a thickness between thirty and sixty microns (30 and 60 μm) formed during this time, this again demonstrating the good tissue compatibility.

Stimulation electrodes of the type illustrated in FIG. 1 were also implanted in dogs' hearts. After 6 weeks, analysis showed that the electrodes were surrounded with connecting tissue having a thickness of less than 100 microns. The employed electrode material is thus bodily compatible.

The inventive electrode can also exhibit a plurality of regions that are provided with a porous layer. These regions then alternate with regions that exhibit no porous layer. Having the current density rise in specific directions can be achieved by means of such a geometrical disposition.

It will be apparent that many modifications and variations may be made without departing from the scope of the teachings and concepts of the present invention.

We claim as our invention:

1. An electrode for medical applications comprising an electrically conductive carrier material and a porous layer defining an active region, said porous layer being of a material comprised of at least one compound selected from the group consisting of a carbide, nitride or carbonitride of at least one of the metals titanium, vanadium, zirconium, niobium, molybdenum, hafnium, tantalum or tungsten, said porous layer having a layer thickness between one micron and one hundred microns.

2. An electrode as claimed in claim 1, wherein a dense nonporous layer of a material corresponding to the material of the porous layer is situated between the carrier material and the porous layer.

3. An electrode as claimed in claim 2, wherein the dense layer has a layer thickness between two and ten microns.

4. An electrode as claimed in claim 1, with said electrode having a plurality of active regions each having a porous layer comprised of at least one of said compounds, the regions having said porous layer separated from one another by regions without a porous layer.

5. An electrode as claimed in claim 1, wherein the carrier material is titanium.

6. An electrode as claimed in claim 1, wherein the carrier material is platinum.

7. An elesurode as claimed in claim 1, wherein the porous layer has a layer thickness between about five microns and about fifty microns.

8. An electrode as claimed in claim 7, wherein the carrier material is titanium.

9. An electrode as claimed in claim 7, wherein the carrier material is platinum.

10. An electrode as claimed in claim 7, wherein a dense nonporous sealing layer comprised of at least said one of said compounds in the porous layer is disposed between the carrier material and the porous layer.

11. An electrode as claimed in claim 10, wherein the dense nonporous sealing layer has a layer thickness between two and ten microns.

12. An electrode system for medical applications comprising an implantable stimulation electrode, said implantable stimulation electrode comprising an electrically conductive carrier material and at least one active region formed of a porous exposed layer exposed to bodily fluids, said porous exposed layer being of a material formed of at least one compound having the formula MeX, where Me is at least one of the metals selected from the group consisting essentially of titanium, vanadium, zirconium, niobium, molybdenum, hafnium, tantalum and tungsten, and where X is selected from the group consisting essentially of at least one of carbon and nitrogen, said porous exposed layer having a layer thickness permeable to bodily fluids which is between about one micron and about one hundred microns in depth.

13. An electrode system according to claim 12, with said porous exposed layer of said implantable stimulation electrode having a layer thickness about five microns and about fifty microns.

14. An electrode system according to claim 12, with said electrically conductive carrier material having a dense nonporous sealing layer isolating said carrier material from bodily fluids, said dense nonporous sealing layer being of a material corresponding to the material of said porous exposed layer, said porous exposed layer being applied on said dense nonporous sealing layer.

15. An electrode system according to claim 14, wherein said dense nonporous sealing layer has a layer thickness between two and ten microns.

16. An electrode system according to claim 12, with said implantable stimulation electrode having a plurality of separate active regions each formed with a porous exposed layer of said material and having said layer thickness, and said porous exposed layers being separated from one another by regions without a porous exposed layer.

* * * * *

EXHIBIT E

United States Patent [19]

Botvidsson et al.

[11] Patent Number: 4,611,604

[45] Date of Patent: Sep. 16, 1986

[54] BIPOLAR ELECTRODE FOR MEDICAL APPLICATIONS

[75] Inventors: Lars Botvidsson, Jaerfaella, Sweden; Konrad Mund, Uttenreuth, Fed. Rep. of Germany

[73] Assignee: Siemens Aktiengesellschaft, Berlin & Munich, Fed. Rep. of Germany

[21] Appl. No.: 569,980

[22] Filed: Jan. 11, 1984

[30] Foreign Application Priority Data

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[51] Int. Cl.⁴ A61N 1/04

[52] U.S. Cl. ..... 128/784; 128/419 P

[58] Field of Search ..... 128/419 P, 784-785

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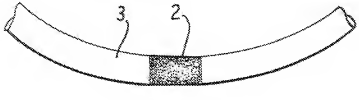
Primary Examiner—William E. Kamm

Attorney, Agent, or Firm—Hill, Van Santen, Steadman & Simpson

[57] ABSTRACT

In order to improve the mechanical properties in the area of the passive electrode given bipolar electrodes, the active region of the passive electrode exhibits a surface layer that has a high double layer capacitance at the phase boundary with the body fluids. The size of the passive electrode can be considerably reduced as a result. Particularly suitable as the surface layer is a porous layer consisting of a carbide, nitride or carbonitride of at least one of the metals titanium, vanadium, zirconium, niobium, molybdenum, hafnium, tantalum or tungsten. A layer of activated carbon with a surface having a porous microstructure or, in the simplest case, a roughened surface are also suitable.

11 Claims, 3 Drawing Figures



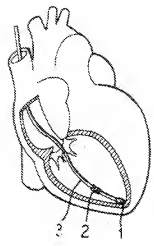


FIG. 1

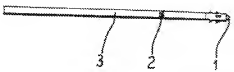


FIG. 2

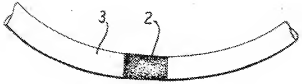


FIG. 3

BIPOLAR ELECTRODE FOR MEDICAL APPLICATIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

Reference is made to a copending application U.S. Ser. No. 569,832 filed Jan. 11, 1984 in the names of Konrad Mund, Helmut Freller and Friedrich Hoersauf, entitled "Electrode for Medical Applications" and to a copending application U.S. Ser. No. 569,979 filed Jan. 11, 1984 in the names of Hakan Elmqvist and Konrad Mund, entitled "Heart Pacemaker System".

BACKGROUND OF THE INVENTION

The invention relates to a bipolar electrode for medical applications, particularly an implantable heart pacemaker electrode, comprising an insulated conductor system, at least one active electrode and a passive electrode disposed along the conductor system at an interval from said active electrode.

In the case of unipolar heart pacemaker treatment, problems often occur with muscle stimulations and/or muscle inhibitions at the housing of the heart pacemaker, said housing usually representing the passive electrode in the electrode system. A possible solution of this problem, as known, resides in utilizing a bipolar electrode system, i.e. of disposing the passive electrode in the proximity of the active electrode(s) inside of the heart. There is an effort to reduce the impedance of the electrode system due to the small distance between the active and passive electrodes. Known passive electrodes consist, for example, of a cylindrical body of a platinum/iridium alloy having a surface area of approximately 50 mm^2. Due to the relatively low double layer capacitance of platinum/iridium (10 $\mu F/cm^2$, 1 kHz), this electrode must have such a large surface area in order to keep the polarization losses within justifiable limits.

Considerable mechanical problems arise, however, due to the large dimensions of the passive electrode. Imagining, for example, an insulated electrical conductor 3 mm in diameter, then the cylindrical body of the passive electrode must be about 5 mm long in order to have the required surface area. That produces a considerable stiffening of the otherwise extremely flexible electrical conductor in the proximity of the active electrode. When, for example, it is a matter of a heart ventricle electrode which is to be applied in the tip of the left heart ventricle, then the passive electrode likewise lies in this heart ventricle. Given the large number of bends that this electrical conductor is exposed to, such a pronounced stiffening represents a great burden that increases the risk that damage to the insulation or a break of the conductor will occur in the proximity of the stiffening.

SUMMARY OF THE INVENTION

A principal object of the present invention is to reduce the surface area of the passive electrode given unaltered or even reduced polarization losses and to thus considerably reduce the mechanical stresses of the electrode in this region.

This object is inventively achieved in that at least the active region of the passive electrode has a surface layer that provides a high double layer capacitance at the phase boundary with the body fluids. This high double layer capacitance insures a low electrochemical impedance and produces only a slight polarization rise during the stimulation pulses. This reduction in electrochemical impedance and consequent reduction in polarization losses can be exploited for reducing the surface area of the passive electrode and thus reducing the mechanical stresses of the electrode.

To that end, the passive electrode can advantageously have a roughened surface or consist overall of a porous material, for example of a sintered metal alloy. It is likewise possible to provide the surface of the passive electrode with a layer of activated glassy carbon that has an extremely high double layer capacitance of up to 0.1 F/cm^2.

A particularly advantageous passive electrode is obtained in that the surface layer is provided by a porous layer of a carbide, nitride or carbonitride of at least one of the metals titanium, vanadium, zirconium niobium, molybdenum, hafnium, tantalum or tungsten. The porous carbide, nitride or carbonitride layers are situated on an electrically conductive carrier material, for example platinum, titanium or a metal alloy such as Elgiloy. The double layer capacitances attainable therewith and the surface area reductions possible as a result thereof lie on approximately the same order as given by glassy carbon layers. In terms of manufacturing technology, however, these porous carbide, nitride and carbonitride layers are to be preferred.

In order to avoid material-associated differential potentials, it is provided in another development of the invention that a dense nonporous sealing layer of a material corresponding to the material of the porous layer is situated between the carrier material and said porous layer.

The double layer capacitances of the inventive, passive electrodes are higher than those of known electrodes by a factor of about 10 through 100 so that a significant reduction of the surface area of the passive electrode is possible. This electrode practially shrinks to a narrow ring that hardly changes the mechanical properties of the conductor system at all, i.e. the high elasticity of the electrode line is largely guaranteed even in the area of the passive electrode.

In addition to the improved mechanical properties, the electrochemical impedance of the overall electrode system can also be reduced with the assistance of the inventive passive electrode depending on the size of the reduction in surface area that is selected, whereby the sensitivity of the system is further enhanced.

An examplary embodiment of the inventive bipolar electrode system is described and explained below with reference to the accompanying sheet of drawings; and other objects, features and advantages will be apparent from this detailed disclosure and from the appended claims.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a somewhat diagrammatic illustration of a bipolar electrode system in accordance with the present invention and showing the passive electrode emplaced in the left ventricle of the heart.

FIG. 2 is a somewhat more detailed showing of the implanted electrode system of FIG. 1; and

FIG. 3 is a partial further enlarged view of illustrating an active region of the passive electrode applied to the insulated covering of the electrode cable of FIGS. 1 and 2.

DETAILED DESCRIPTION

FIG. 1 shows a bipolar electrode system wherein an implanted heart pacemaker external to the heart is connected with the implanted electrodes 1 and 2 via a flexible cable 3. The passive electrode 2 is shown as being implanted in the same chamber of the heart as the active stimulation electrode 1. The passive electrode 2 is disposed along the insulated covering of the cable 3 in proximity to the active electrode 1 and inside of the heart and is electrically connected with one of the conductors of cable 3 in any suitable manner. The insulated covering of cable 3 may have an outside diameter of three millimeters, and as indicated in FIG. 2, the length of the cylindrical active region 2 of the passive electrode may be less than the outside diameter of the cable 3 to which the passive electrode is applied. Thus the passive electrode 2 which is of any of the forms described herein does not result in a material stiffening of the otherwise extremely flexible electrical cable 3 in the proximity of the active electrode 1.

Specifically, the passive electrode 2 in each of the forms described herein is preferably in the shape of a narrow ring having a length which is a minor fraction (e.g. one-tenth) of five millimeters and hardly changes the mechanical properties of the cable 3 so that the high flexibility of the cable 3 is largely guaranteed even in the area of the passive electrode 2.

The drawings are to be understood as illustrating each of the embodiments defined in the claims.

In FIGS. 1–3, the passive electrode region 2 can advantageously have a roughened surface or consist overall of a porous material, for example of a sintered metal alloy. It is likewise possible to provide the surface of the passive electrode with a layer of activated glassy carbon that has an extremely high double layer capacitance of up to 0.1 F/cm².

A particularly advantageous passive electrode is obtained in that the surface layer is provided by a porous layer of a carbide, nitride or carbonitride of at least one of the metals titanium, vanadium, zirconium, niobium, molybdenum, hafnium, tantalum or tungsten. The porous carbide, nitride or carbonitride layers are situated on an electrically conductive carrier material, for example platinum, uranium or a metal alloy such as Elgiloy. The double layer capacitances attainable therewith and the surface area reductions possible as a result thereof lie on approximately the same order as given by glassy carbon layers. In terms of manufacturing technology, however, these porous carbide, nitride and carbonitride layers are to be preferred.

In order to avoid material-associated differential potentials, it is provided in another development of the invention that a dense nonporous sealing layer of a material corresponding to the material of the porous layer as situated between the carrier material and said porous layer.

The double layer capacitances of the inventive, passive electrodes are higher than those of known electrodes by a factor of about 10 through 100 so that a significant reduction of th surface area of the passive electrode is possible. This electrode practially shrinks to a narrow ring (as shown in FIG. 2) that hardly changes the mechanical properties of the conductor system as all. i.e. the high elasticity of the electrode line 3 is largely guaranteed even in the area of the passive electrode 2.

In addition to the improved mechanical properties, the electrochemical impedence of the overall electrode system can also be reduced with the assistance of the inventive passive electrode depending on the size of the reduction in surface area that is selected, whereby the sensitivity of the system is further enhanced.

The thin, porous nitride, carbide or carbonitride layers are preferably applied by means of ion plating, i.e. by means of physical vapor deposition onto the carrier material such as titanium or platinum serving as the substrate. Dense nonporous sealing layers can thereby first be deposited followed by porous layers of the same material in a continuous fabrication process by means of changing the vapor pressures.

Elgiloy is a corrosion resisiant alloy having the following components: cobalt, chromium, nickel, iron, molybdenum, manganese, carbon and beryllium.

A high double layer capacitance is a capacitance between the passive electrode at the active region and bodily fluid which permeates the active region which lies in the range from about ten millifarads per centimeter squared and about one hundred millifarads per centimeter squared when measured with a pulse repetition frequency of one hertz as described.

Titanium nitride-coated titanium sheets, for example, served for the determination of the electrochemical properties, having been investigated in a half cell arrangement with 0.15M NaCl as the electrolyte. A smooth platinum sheet served as cooperating electrode; an Ag|Cl electrode was employed as the reference electrode. The electrodes were connected to a potentiostat and the potential values were converted and related to the potential of the reversible hydrogen electrode (H_2 electrode). The electrodes thereby set a potential of $\phi/H_{2\,rev}$=0.89 V. (The specification $\phi/H_{2\,rev}$ denotes a potential referred to the reversible hydrogen electrode.) Under potentio-dynamic load, with a voltage rate of change of ten millivolts per second (10 mV/s), one observed a constant current in the center of the interval $0.5 \phi/H_{2\,rev} \leq 1$ V. Therefrom a double layer capacitance of 68 mF/cm² occurred at the beginning of the load, and this did not change over a load duration of eighty-eight hours (88 h). The investigations showed that no corrosion occurred up to a potential of 1.1 V; the electrodes are thus sufficiently stable.

The roughened surface layer at the active region can be produced by roughening the exterior metallic surface of the passive electrode at the active region to provide at least twice the area of contact with bodily fluids as would be provided by a smooth metal surface of configuration corresponding to that of the active region. The roughened surface may be permeated by bodily fluids to a depth between about one micrometer (one micron) and about one hundred micrometers, this depth being termed the "layer thickness".

The active region may also be comprised of activated carbon with a microporous exposed surface permeated by bodily fluids to a depth between about one micrometer (one micron) and about one hundred micrometers, this depth being termed the "layer thickness". Within the scope of the present disclosure, an activated surface is understood to mean a surface with a microporous, i.e., a roughened surface.

The term "mixed potentials" refers to potentials produced because of the presence of different materials—i.e. material associated potentials.

Although modifications and changes may be suggested by those skilled in the art, it is the intention of the

inventors to embody within the patent warranted hereon all changes and modifications as reasonably and properly come within the scope of their contribution to the art.

We claim as our invention:

1. A bipolar electrode system for medical applications comprising an implantable heart pacemaker with an insulated flexible conductor system having at least one active electrode, a passive electrode disposed along the conductor system at an interval from the active electrode, and means for providing selected double layer capacitance at a phase boundary between a surface layer of said passive electrode and surrounding body fluids without substantial impairment of the flexibility of said conductor system, said means including a carrier material and an active region connected therewith forming said passive electrode, at least said active region of said passive electrode forming said surface layer exposed to said body fluids and providing said double layer capacitance at the phase boundary with the body fluids in the range of from about 10 millifarads per centimeter squared to about 100 millifarads per centimeter squared as measured at one hertz and said surface layer having a length along said conductor system selected for maintaining flexibility of said conductor system.

2. A bipolar electrode system as claimed in claim 1 wherein the surface layer is formed by a roughened surface of the passive electrode.

3. A bipolar electrode system as claimed in claim 1 wherein the active region of the passive electrode comprises sintered material having high porosity and a large internal surface area at least at a surface region providing said surface layer.

4. A bipolar electrode system as claimed in claim 1 wherein the surface layer is comprised of activated carbon with a porous microstructure.

5. A bipolar electrode system as claimed in claim 1 wherein the surface layer is comprised of a porous layer consisting of a carbide, nitride or carbonitride of at least one of the metals titanium, vanadium, zirconium, niobium, molybdenum, hafnium, tantalum or tungsten.

6. A bipolar electrode system as claimed in claim 1 wherein the surface layer is comprised of a porous layer consisting of a material selected from the group consisting of a carbide, nitride or carbonitride of at least one of the metals titanium, vanadium, zirconium, niobium, molybdenum, hafnium, tantalum and tungsten, and wherein a dense nonporous layer of a material corresponding to that of the porous layer is situated between the carrier material and said porous layer.

7. A bipolar electrode system as claimed in claim 6 wherein the dense nonporous layer has a layer thickness between about two microns and about ten microns.

8. A bipolar electrode system as claimed in claim 1 wherein the surface layer has a layer thickness between one micron and 100 microns.

9. A bipolar electrode system as claimed in claim 1 wherein the surface layer has a layer thickness between one micron and 100 microns, and wherein a dense nonporous layer of a material corresponding to that of the porous layer is situated between the carrier material and said porous layer.

10. A bipolar electrode system as claimed in claim 1 wherein the surface layer has a layer thickness between about five microns and about twenty microns.

11. A bipolar electrode system as claimed in claim 1 wherein the surface layer has a layer thickness between about five microns and about twenty microns, and wherein a dense nonporous layer of a material corresponding to that of the porous layer is situated between the carrier material and said porous layer, said dense nonporous layer having a layer thickness between about two microns and about ten microns.

* * * * *

EXHIBIT F

United States Patent [19]

Baker, Jr.

[11] Patent Number: 4,762,136

[45] Date of Patent: * Aug. 9, 1988

[54] **LOW POLARIZATION PACING ELECTRODES FOR CAPTURE VERIFICATION**

[75] Inventor: Ross G. Baker, Jr., Houston, Tex.

[73] Assignee: Intermedics, Inc., Angleton, Tex.

[*] Notice: The portion of the term of this patent subsequent to Jul. 14, 2004 has been disclaimed.

[21] Appl. No.: 16,379

[22] Filed: Feb. 19, 1987

[51] Int. Cl.[4] A61N 1/05

[52] U.S. Cl. ..... 128/786; 128/785; 128/419 P

[58] Field of Search 128/784–786, 128/419, 642

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Primary Examiner—Lee S. Cohen
Attorney, Agent, or Firm—Leitner, Greene & Christensen

[57] **ABSTRACT**

An electrode for use in cardiac pacing has a substrate composed of a material conventionally employed for pacing electrodes, and a surface layer or film of iridium oxide overlying the substrate. For use as a stimulating cathodic electrode and a sensing electrode, the iridium oxide layer is arranged to be in cardiac tissue stimulating relationship when the electrode is in proper position with respect to the patient's heart. The electrode impresses electrical stimuli on the excitable myocardial tissue, and at the completion of each stimulus, the electrode is capable of abruptly sensing, within an interval less than 100 *ms* thereafter, the electrical activity of the heart in response to the stimulus to verify capture. The surface of the electrode may be provided with recesses to which the iridium oxide layer may be confined. An iridium oxide layer may be provided on both the cathode and the anode for efficient transduction at the electrode-electrolyte interface formed by the surface of the iridium oxide layer and the surrounding body fluid and tissue.

10 Claims, 2 Drawing Sheets

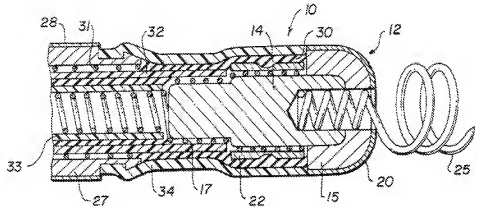
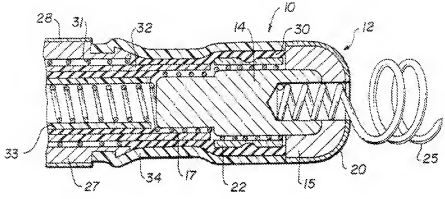


FIG1



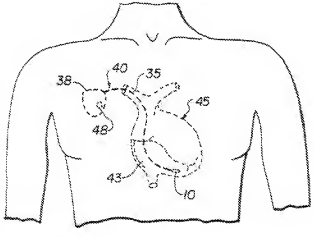
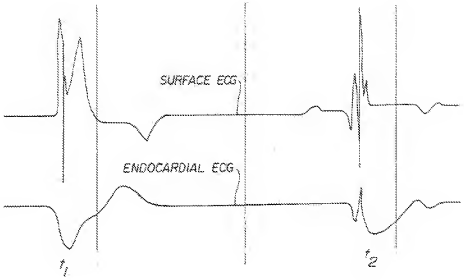


FIG2

FIG 3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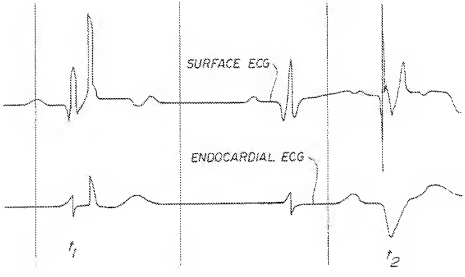
ENDOCARDIAL ECG
t_1
t_2

FIG 4


SURFACE ECG
ENDOCARDIAL ECG
t_1
t_2

LOW POLARIZATION PACING ELECTRODES FOR CAPTURE VERIFICATION

BACKGROUND OF THE INVENTION

The present invention relates generally to artificial cardiac pacing, and more particularly to improved pacing electrodes for stimulating and sensing electrical activity of the heart, and to pacing lead assemblies incorporating such electrodes.

The sinoatrial (S-A) node of the normal mammalian heart acts as the natural pacemaker by which rhythmic electrical excitation is developed and propagated to the atria. In response, the atrial chambers contract, pumping blood into the ventricles. The excitation is propagated through the atrioventricular (A-V) node, which imposes a delay, and then via the conduction system consisting of the bundle of His and Purkinge fibers to the ventricular myocardium, causing contraction and the pumping of blood from the ventricles. Disruption of this natural pacing/propagation system occurs as a result of aging and disease.

Where the human patient has an abnormally slow or abnormally rapid heart rate, or the rate is irregular, it is customary for the cardiologist to prescribe implantation of an artificial cardiac pacemaker selected according to the specific patient's needs. In its simplest form, the cardiac pacemaker consists of a pulse generator with a battery pack, and a lead assembly. The lead assembly includes a pacing electrode to be positioned in stimulating relationship to excitable myocardial tissue, and an insulated electrical coil interconnecting the pulse generator and the pacing electrode to deliver the electrical pulses to the electrode to stimulate the tissue. The electrical circuit is completed via a second electrode (the indifferent or reference electrode), which is connected to a point of reference potential for the cardiac pacemaker, and through the body tissue and fluids. The stimulating electrode may also be used as a sensing electrode by coupling to a detection circuit to sense the electrical activity of the heart. The entire lead/electrode assembly is often referred to simply as the "lead".

In the instant specification, the pacing electrode is sometimes referred to as the stimulating cathodic electrode, the stimulating electrode, or the cathode, and the indifferent electrode is sometimes referred to as the reference electrode, the anodic electrode, or the anode. It will be understood, however, that electrical activity takes place at each electrode during pacing, and that the coupling may be such that each electrode acts, at different times, as cathode or anode.

The lead of choice for use with the cardiac pacemaker is an endocardial catheter, which is readily inserted transvenously to introduce the stimulating electrode into the cardiac chamber to be paced. In contrast, an epicardial lead requires thoracic surgery to affix the electrode to the surface of the heart. Various forms of active or passive fixation may be employed to maintain the stimulating electrode in proper position relative to the excitable heart tissue, such as sutures (epicardial), a corkscrew or flexible barbs, hooks or tines fastened to the lead in proximity to the electrode.

The cardiac pacemaker may employ unipolar or bipolar stimulation, depending on the preference of the physician and the needs of the patient. For unipolar stimulation, the anode is located remote from the heart, and typically comprises the metal case or portion thereof that houses the batteries, pulse generator and other electronic circuitry of the pacemaker. For bipolar stimulation, the two electrodes are in close proximity, typically with the cathode being at the tip and the anode spaced slightly back from the tip as a ring electrode on the lead.

The cardiac pacemaker may operate in any of several different response modes, including asynchronous, or fixed rate; inhibited, in which stimuli are generated in the absence of specified normal cardiac activity; or triggered, in which the stimuli are delivered in response to specified cardiac activity. In each of these modes, output pulses from the pulse generator are delivered via the lead for electrical stimulation of excitable myocardial tissue at or near the site of the cathode, thereby producing the desired rhythmic contractions of the affected chamber. Since stimulation is attributable to current density, small area stimulating electrodes will suffice. The current required to produce a given current density decreases in direct proportion to the active area of the electrode. Small area cathodic electrodes therefore serve to prolong battery life, and increase the interval between required surgical replacements.

In essence, stimulation requires that the electric field be of sufficient field strength and current density to initiate contraction of excitable myocardial tissue at the cathode site. The minimum electrical impulse necessary to achieve this is referred to as the stimulation threshold. The greater the efficiency of the cathode in impressing the electric field on the tissue, the smaller the amplitude and/or duration of (and the energy contained in) the pacing pulse required to achieve the stimulation threshold. Accordingly, highly efficient, low threshold electrodes conserve energy and prolong battery life. Because greater electrode efficiency reduces energy required for stimulation, it may be a factor in reducing injury to tissue at the stimulation site.

Cardiac pacing may be achieved with anodal rather than cathodal stimulation, but the stimulation threshold is higher because the polarizing force of the stimulating electric field on ions at the surface of membranes of the excitable myocardial cells reduces transmembrane potential on the side of each affected cell furthest from the anode, at a point of relatively lower field intensity; in contrast to reduction of the potential at the near side with cathodal stimulation.

Regardless of the type of pacemaker implanted, from the simple fixed rate device to the complex dual chamber pacing/sensing devices and the latest physiologic pacers, it is important to ascertain that the stimulus is having the desired effect. Pulse generation which causes contraction of the selected chamber is termed "capture", and the method of determining that the pacer stimuli are achieving capture is called "capture verification". Capture verification techniques are based on detecting the potential evoked when the heart is captured. If there is no capture, there is no evoked potential, and the amplitude and/or duration of the stimulating pulse must then be adjusted to assure consistent capture. It follows that each time the heart is paced, the cardiac electrical activity may be monitored to detect the presence of the evoked potential and thereby verify capture.

In practice, however, capture verification is fraught with problems, one of the more significant being of a signal-to-noise nature in which the signal sought to be detected is masked by after-potentials attributable to electrode polarization. After the stimulating pulse is

delivered, the electrode must "settle down" to allow detection of the evoked potential indicative of capture. This requires a suitable period of delay, which itself precludes the desired detection. Accordingly, some capture verification techniques seek to filter the signal from the masking after-potential, necessitating additional circuitry and space.

SUMMARY OF THE INVENTION

In copending U.S. patent application Ser. No. 838,607, filed Mar. 11, 1986, now U.S. Pat. No. 4,679,572, entitled "Low Threshold Cardiac Pacing Electrodes" (the "copending Ser. No. 838,607 application"), and assigned to the same assignee as this application, I disclose a stimulating electrode for cardiac pacing or other cardiac stimulation functions, in which an iridium oxide layer is formed on the electrode surface to provide a considerable reduction in the stimulation threshold as compared to electrodes and electrode materials and compositions previously employed in the cardiac pacing field. The iridium oxide coating provides advantages in cardiac electrodes used as either cathodes or anodes. Among other advantages of such electrodes, the lower threshold may be a factor in reducing injury to myocardial tissue at the stimulation site; and iridium oxide appears to possess greater physical integrity and superior charge transfer capability per unit area than materials heretofore commonly employed for cardiac stimulation applications, including specialized coatings such as platinum black.

As noted in the copending Ser. No. 838,607 application, iridium oxide electrodes had previously been used in various other applications, such as in electrochromic displays (e.g., see Dautremont-Smith et al., "Electrochromic Cells with Iridium Oxide Display Electrodes", *Solid State Ionics* 2 (1981) pp. 13-18); and including certain medical applications, such as for measuring tissue impedances (e.g., see Gielen et al., "Comparison of electrode impedances of Pt, PtIr (10% Ir) and Ir-AIROF electrodes used in electrophysiological experiments", *Medical and Biological Engineering & Computing*, January 1982, pp. 77-83); for measuring acidity in the upper gastro-intestinal tract (e.g., see Papeschi et al., "The Iridium/Iridium oxide electrode for in vivo measurement of oesophageal and gastric pH", *Journal of Medical Engineering and Technology*, Vol. 8, No. 5, September-October 1984, pp. 221-223); and for measuring acidity changes in the blood (e.g., see Papeschi et al., "An iridium/iridium oxide electrode for in vivo monitoring of blood pH changes", *Journal of Medical engineering and Technology*, Vol. 5, No. 2, March 1981, pp. 86-88, and Cammilli et al., "Preliminary Experience with the pH-triggered Pacemaker", *PACE*, Vol. 1, October-December 1978, pp. 448-457). In the Cammilli et al. publication, the authors reported on the use of an iridium oxide electrode for continuous in vivo detection of variations of mixed venous blood pH. According to the article, a rapid decrease of blood pH was utilized as a measure of variation of the patient's metabolic rate and employed to produce an appropriate variation in the stimulation rate for physiological pacing.

Such reports neither teach nor suggest using an iridium oxide electrode for stimulating or sensing electrical activity of the heart. Indeed, in the medical applications of iridium oxide electrodes previously reported, any stray electrical signals would have been deemed as interfering with and undesirable to the purpose for which the electrodes were being used.

Although iridium oxide electrodes have been used more recently in electrophysiological experiments, such as for neuroelectrical experimentation with brain activity in small animals, the proposal for such use was attributable to an absolute requirement for extremely fine electrode wires, with active surface areas on the order of 20 square microns. It had been found that even platinum electrodes of such tiny size disintegrated on the passage therethrough of relatively low levels of current. It was found that an iridium oxide coating was capable of withstanding the necessary current without significant deterioration. In contrast to the relatively tiny surface areas of concern in these physiological experiments, electrodes for the stimulation of excitable cardiac tissue, or for the detection of cardiac electrical activity, require considerably greater surface areas.

The copending Ser. No. 838,607 application notes finding that iridium oxide possesses an extraordinary capability to perform as a charge flow transducer between media exhibiting different charge flow mechanisms, and, despite its relatively inferior characteristics as an electrical conductor compared to conventional pacing electrode materials, that certain properties of iridium oxide make it particularly effective for application in electrodes for stimulating and/or sensing electrical activity of the heart. This appears to arise, in part, from the two basic mechanisms for current flow across a pacing electrode. One is the purely capacitive mechanism by which electron flow away from the cathode causes electrical charges in the solution at the electrode-electrolyte interface to orient themselves such that a displacement current occurs through the electrolyte, i.e., because the electrolyte is an ionic medium, the slight displacement of the ions in reorientation creates a charge flow. When the electrical potential across the electrode-electrolyte interface is sufficiently large, chemical reactions begin to occur and current flows. At that point, the mechanism is no longer capacitive. With conventional electrode materials, the chemical reactions are substantially irreversible.

Iridium oxide demonstrates a capacity to readily accept electrons out of an electrolytic solution, and thus can operate as a highly efficient transducer between an electron flow conductor—such as a metal electrode—and an ionic flow conductor—such as the saline fluid of the body.

Iridium oxide may be deposited as a relatively thick porous layer on a metal substrate for use as a pacing electrode, in both stimulating and sensing applications. The porous structure accommodates water from the body saline. In a typical reaction involving a conventional electrode, a negative potential on the electrode repels electrons, and hydrogen is released from the water in the process. In contrast, with an iridium oxide layer relatively tiny potential differences across the electrode-electrolyte interface are effective to produce the reactions and consequent current flow, while the pores trap the reaction products that would otherwise diffuse away and might injure tissue in the vicinity of the stimulation site. More importantly, with the iridium oxide electrode the reactions are reversible upon reversal of the voltage.

A capacitive effect occurs with an iridium oxide coated electrode, but to a considerably lesser extent than that occurring, for example, with a platinum electrode. Rather, the interface across the iridium oxide surface appears to be primarily resistive. Thus, an iridium oxide coated pacing electrode exhibits lower polar-

ization than is observed with conventional pacing electrodes, which is to say that the voltage buildup at the interface is smaller for a given charge flow through the iridium oxide electrode.

The present invention takes advantage of the low polarization and related attributes of an iridium oxide coated pacing electrode. The low polarization and resultant relatively small voltage buildup at the interface not only make available more energy from each pacing pulse for tissue stimulation, but importantly allow the detection of cardiac electrical activity virtually immediately after stimulation. Therefore, an iridium oxide coated electrode may be used for both stimulation and sensing of cardiac activity to effect low threshold capture and, as a result of the electrode's rapid recovery from the after-potential which follows delivery of the stimulus, to provide virtually instantaneous verification of capture. It is noteworthy that such capture verification is achieved without the need for special filter circuitry or other apparatus beyond the usual detection circuit.

Although the reasons for the highly efficient behavior of iridium oxide as a charge flow transducer between media exhibiting different charge flow mechanisms are not fully understood, it further appears to be attributable to the numerous oxidation states within a film of the material. Those oxidation states seem to be relatively stable, with low activation energies, and, therefore, the layer tends to perform more as a resistor than a capacitor. The result is that current flow is facilitated, but without the buildup of residual voltages. The primarily resistive nature of the electrode-electrolyte interface enables rapid dissipation of any after-potential, in contrast to the usual resistive-capacitive mechanism encountered with conventional pacing electrodes by which the passage of current causes a capacitive buildup of voltage and an R-C decay. Whatever may be the reasons for this advantageous behavior of the iridium oxide film, the virtual absence of residual voltages serves to eliminate the masking delay that inevitably follows cardiac stimulation with conventional pacing electrodes, and permits reliable sensing of the evoked potential attributable to capture.

Accordingly, it is a principal object of the present invention to provide improvements in capture verification for cardiac pacing.

In a preferred embodiment of the invention, an iridium oxide layer is provided on the exposed surface of a pacing electrode adapted to be positioned in electrically stimulating and sensing relationship with the excitable myocardial tissue at a pre-selected stimulation site. The underlying substrate of the electrode may be composed of any conventional material for pacing electrode applications, such as titanium, and is preferably but not necessarily a porous structure. The substrate surface may be grooved, dimpled or rippled to provide recesses to which the iridium oxide film may be confined to remove those regions of highest current density from direct contact with the tissue.

The iridium oxide coated electrode is electrically connected to a conductive coil within the lead, which itself is coupled both to the output circuit of the pulse generator and to the detection circuit. The latter is connected at all times but the system logic ignores any input during the refractory period. The pulse generator delivers a pulse to the heart through the stimulating and indifferent electrodes via a coupling capacitor which is then actively discharged by reversal of current flow. The sense amplifier is disconnected during pacing and until the active discharge time elapses.

Further objects of the invention are to provide a pacing electrode for both stimulating and sensing electrical activity of the heart, with low polarization and reduced residual voltage to preclude masking of the evoked potential following capture and, thereby, to enable relatively rapid sensing of the evoked potential for capture verification; and to provide improved methods for artificial pacing and capture verification.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and still further objects, features, aspects and advantages of the present invention will become apparent to those of ordinary skill in the field to which the invention pertains from a consideration of the following detailed description of certain preferred embodiments, taken in conjunction with the accompanying drawings, in which:

FIG. 1 is a simplified cross-sectional view of a pacing electrode assembly according to the invention, taken along the axis of the configuration, which is circular in transverse cross-section;

FIG. 2 is a simplified representation of an alternative embodiment of a pacing electrode assembly as part of a lead assembly arranged for unipolar stimulation, in a cardiac pacemaker implanted in the body; and

FIGS. 3 and 4 are electrograms taken from test dogs, respectively using conventional electrodes and iridium oxide coated electrodes for stimulation and sensing, in which the top portion of each FIG. represents a surface electrogram and the bottom portion an electrogram taken between the indifferent electrode and the tip electrode of an implanted lead assembly.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to FIG. 1, electrode assembly 10 is part of and located at the distal end of a pacing lead assembly (to be described more fully in connection with FIG. 2). The proximal end of the lead assembly is conventionally arranged for connection to the pulse generator of an implantable cardiac pacemaker. The electrode assembly shown in FIG. 1 is a simplified depiction since there is no need to illustrate those details of electrode structure which are well known.

Assembly 10 is configured for endocardial positioning, in which tip electrode (cathode) 12 is adapted to be placed in electrically stimulating relationship with excitable cardiac tissue within a selected chamber of the heart. Substrate 18 of tip 12, and integral stem 14, are composed of any conventional electrode materials, such as platinum, platinumiridium alloy, iridium, tantalum, or titanium, by way of example; and preferably, titanium. A coil 17 of electrically conductive wire within the lead assembly is maintained in solid electrical contact with tip 12 by means of a metal sleeve 22 crimping the coil against the stem. A corkscrew 25 may be affixed to the electrode assembly in a conventional manner to provide active fixation of the stimulating electrode to the myocardium after the electrode has been positioned properly in the selected chamber.

The surface of the cathodic tip electrode 12 is coated with a film or layer 20 of iridium oxide, which may be an AIROF (anodized iridium oxide film), SIROF (sputtered iridium oxide film), TIROF (thermal iridium oxide film), or a layer formed in any other suitable manner. The particular process by which the iridium oxide

film or layer is provided on the substrate forms no part of the present invention. The iridium oxide layer may have a thickness of approximately 200 nanometers, although any layer thickness exceeding about 100 nanometers appears to be satisfactory to obtain the desirable results. In one embodiment, the layer had an exposed surface area of approximately 8.5 square millimeters. Preferably, the substrate 15 of tip 12 has a porous surface structure, such that the iridium oxide coating assumes the lacework contour of the surface and promotes ingrowth of cardiac tissue to reduce abrasion of the adjacent tissue.

Stem 14 and substrate 15 may be formed integrally or separately (in the latter case, the two are then pressed together and bonded) by conventional powder metallurgy process, in which powdered titanium is packed into a mold, compressed, and thereafter sintered at a temperature and for a time sufficient to cause partial melting into a relatively porous electrically conductive structure.

An exemplary preferred process for forming a TIROF film on porous titanium tip electrode substrates is as follows. The electrode tips are etched in hot 10% oxalic acid, 100° C. for 30 minutes; thereafter rinsed in distilled water and placed in an iridium solution with only the tip portions to be coated contacted by the solution. The Ir solution is prepared by dissolving 0.4 gram $IrCl_3 \cdot 3H_2O$ in 10 ml 20% HCl, heating the solution to evaporate the HCl down to one-quarter volume and restoring the original volume with absolute isopropanol, the resulting solution to be used within 7 to 14 days. Following a 16 hour soak in this solution, the electrodes are dried at room temperature for one hour, and then annealed at 320° C. for another hour. The steps of soaking, drying and annealing are repeated, and the electrodes are then annealed again at 320° C. for a period of from 3 to 6 hours.

In an exemplary SIROF process, the electrode substrate may be reactively coated with iridium oxide in a conventional diode RF sputtering system. The substrate is initially positioned and maintained in good thermal contact with the water cooled platform of the sputtering system. Any portion of the surface which is not to be coated is suitably masked. Pre-sputtering is performed with an iridium target in pure oxygen at an ambient pressure of about20 microns for approximately 20 minutes to one-half hour. The pressure is then reduced to the range from about 2 to 4 microns, and sputtering is performed with a target power density of about 0.6 to 0.8 watt per square centimeter. The process is continued until an iridium oxide layer of the desired thickness is deposited.

For bipolar stimulation, the electrode assembly includes an anodic electrode 27, preferably of titanium, configured as a ring electrode insulatively spaced behind tip 12 by a sufficient distance to avoid the shunting of current between the edges of the two electrodes. The anode also may be coated with a layer 28 of iridium oxide at its exposed surface, in the same manner as cathodic electrode tip 12. A second coil 31 of conductive wire is maintained in electrical connection with the interior of anode 27 by confining the coil, for example, between the anode and a metal ring (not shown) at the far end of the anode. Coil 31 is part of the lead assembly, and is arranged via a connector (not shown) at the proximal end for coupling the anode to a point of reference potential at the pulse generator. An electrically insulating mass 30 of silicone rubber may be used to encapsulate the internal elements of the electrode assembly, including polyurethane sleeves 32 and 33, and an outer polyurethane sleeve 34 covers the assembly from cathode tip 12 to anode 27 leaving the IrO surfaces of those two electrodes exposed.

Referring now to FIG. 2, a pacing lead assembly 35 includes electrode assembly 10 at its distal end and is connected at its proximal end to appropriate points of electrical potential of the conventional circuitry, including the pulse generator, housed within a metallic case 38. The combination of the circuitry in case 38 and the pacing lead assembly 35 constitutes cardiac pacemaker 40. As shown in FIG. 2, the pacing lead assembly 35 is inserted transvenously until the iridium oxide coated cathodic tip is properly positioned in contact with or adjacent to excitable tissue within the selected chamber; in this example, the right ventricle 43 of the patient's heart 45. Case 28 houses a pulse generator, a detection circuit, the batteries, and other conventional electronic circuitry, and includes an electrical connector mating with the connector at the proximal end of the pacing lead assembly. In practice, the case is implanted in a surgical incision which forms a subcutaneous pouch in the patient's chest, after connection to the lead assembly.

The pacing lead assembly 35 shown in FIG. 2 may be arranged for unipolar stimulation, with the case 38 or a limited region 48 thereof comprising an iridium oxide-coated foil being used as the anode. Of course, in that situation the anodic ring and associated coil of the electrode assembly shown in FIG. 1 would not be present. Region 48 may include a substrate of iridium foil which has been anodized to form an AIROF film thereon, and the uncoated side of the foil then conductively bonded to titanium case 38. Alternatively, region 48 may comprise a titanium or iridium button on which an iridium oxide layer, preferably having a thickness exceeding 100 nanometers, is formed by the preferred process described earlier herein.

In operation of the pacemaker of FIG. 2, stimulating pulses delivered by the pulse generator to the cathodic electrode cause an electric field to be impressed on the myocardial tissue at the cathode site. If the field strength and current density of the electric field is sufficient to reach or exceed the stimulation threshold, capture is achieved. The efficient transduction of the iridium oxide layer on the cathode tip results in considerably lower stimulation thresholds and electrode polarization than may be achieved with pacing electrodes composed of materials heretofore utilized for such applications. Acute stimulation thresholds as low as approximately 0.2 volt have been observed in pacing experiments on test dogs using lead assemblies with iridium oxide coated cathodes.

A stimulating pulse is delivered by the pulse generator to the heart through the circuit which includes the lead, the cathodic electrode, the anodic electrode, the body tissue and fluid. The events leading up to the pacing depend upon the particular type of pacemaker, but in general the pulse is of relatively short duration, e.g., 0.5 ms, for the period of closure of a switch (typically, an NMOS FET) to discharge the main capacitor through a smaller coupling capacitor. The latter is charged in the process, and it is customary to actively discharge the coupling capacitor when the aforementioned switch is opened, by closing another switch (typically, a PMOS FET) to provide a reverse current path for an interval of about 10 ms. The sense amplifier is

unhooked during stimulation and throughout the active discharge interval, but therefter receives signals representing electrical activity sensed by the tip electrode (cathode). With conventional pacing electrodes, electrode polarization may result in a lingering after-potential following delivery of each pacing pulse. The after-potential may continue for hundreds of milliseconds, and, if it extends beyond the refractory period, may easily result in false detection as a cardiac event. In contrast, the low polarization iridium oxide coated pacing electrodes of the presen: invention virtually eliminate after-potentials, and thereby allow sensing of evoked potentials and other valid cardiac events within a relatively short time after stimulation, approximately 25 ms and consistently within the first 100 milliseconds.

Referring now to FIGS. 3 and 4, each of these FIGS. shows an upper trace of a surface ECG, and a lower trace of an endocardial ECG taken across the the indifferent electrode and the stimulating cathodic electrode. The cathode was used for stimulation, and for sensing after the application of stimuli and at all other times. The traces in FIG. 3 were obtained from a test dog in which a lead assembly with a conventional platinum-iridium stimulating electrode was implanted. It will be observed that in the lower trace the two waveforms are confusingly similar, and indeed, appear to indicate capture at both times t_1 and t_2. However, the surface electrogram of the upper trace clearly indicates a pace with captured QRS at time t_1, and a P-wave and QRS complex with a pacing pulse at time t_2 but at that point the tissue is depolarized so there is no capture. In the latter instance it was the after-potential on the elecirode that was detected. Although the traces of FIG. 3 visually allow the trained observer to distinguish between capture and noncapture, the distinction is not readily detected by conventional electronic circuitry. For example, the waveform at time t_2 in the lower trace of FIG. 3 would be detected as capture by a typical level detector.

Referring now to FIG. 4, these traces were obtained from a test dog in which the implanted lead assembly was provided with an iridium oxide coated stimulating electrode. It will be observed here that the lower trace indicates non-capture at time t_1 and capture at time t_2, and that the two are clearly distinguishable by detection circuitry as well.

It will be apparent from the foregoing description that variations are possible without departing from the inventive principles, e.g., use in defibrillation. Accordingly, the invention is to be limited only by the appended claims.

I claim:

1. A lead assembly for use in sensing capture of the heart in conjunction with pacing of the heart, comprising

an electrode having a coating of iridium oxide on a surface thereof adapted to be in electrically coupled relationship with the heart when said lead assembly is implanted in a patient, to provide low polarization whereby the electrode is capable of sensing the evoked potential indicative of capture immediately after the heart is paced, and

electrical conductor means connected to said electrode for electrically coupling said electrode to detecting circuitry of a cardiac pacemaker.

2. The lead assembly of claim 1, in which

the iridium oxide coated surface is porous, and said coating follows the interstices of the porous surface.

3. The lead assembly of claim 1, in which

said iridium oxide coating has a thickness exceeding 100 nanometers.

4. The lead assembly of claim 1, further including

a second electrode having an iridium oxide coating on a surface thereof and insulatively spaced from the first-named electrode, and

a second electrical conductor means connected to said second electrode for electrically coupling said second electrode to the circuitry of said cardiac pacemaker.

5. A cardiac pacemaker for stimulating and sensing electrical activity of a human heart, comprising

a pulse generator means,

a detection circuit means,

means for supplying electrical power to said pulse generator means and said detection circuit means,

an electrode means having a surface layer of iridium oxide to electrically interact with excitable cardiac tissue of said heart when a stimulating pulse is applied thereto and for rapid recovery from after-potentials at said surface layer upon cessation of the stimulating pulse to enable sensing of the potential evoked and verification of capture of the heart by said stimulating pulse, and

a conductor means having a distal end and a proximal end, said distal end electrically connected to said electrode means and said proximal end electrically connected to said pulse generator means and said detection circuit means, for applying stimulating pulses from said generator means to said electrode means and applying evoked potentials sensed by said electrode means to said detection circuit means.

6. The cardiac pacemaker of claim 5, further including a metal case housing said pulse generator means, detection circuit means, and power supply means, and

an indifferent electrode means affixed to said case and having a surface layer of iridium oxide thereon, said indifferent electrode means connected to a point of reference potential of said power supply means to cooperate with the first-named electrode means for unipolar stimulation of the heart.

7. A method of artificially pacing a heart and detecting capture thereof, comprising the steps of

introducing an electrode having an iridium oxide surface layer thereon into cardiac tissue stimulating relationship with the heart,

impressing electrical stimuli on said electrode at a rate within the range selected to provide the desired stimulation of the heart, and

detecting the electrical activity of the heart sensed at the surface of said iridium oxide layer within less than 100 milliseconds after a stimulus to determine whether the heart is captured by said stimulus.

8. The method according to claim 7, wherein

said electrode is introduced transvenously into a selected chamber of the heart to position said electrode with said iridium oxide layer in cardiac tissue stimulating relationship with the endocardium of said chamber.

9. An implantable lead assembly for electrical conduction between an electrical energy processing means and the myocardium of a human heart, said lead assembly comprising

low polarization electrode means having a size and shape configured to be positioned in proximity to the myocardium for impressing electrical stimuli thereon and, abruptly at the completion of a stimulus, for sensing whether the heart is captured by said stimulus by detecting the evoked potential indicative of capture, said electrode means having an iridium oxide coating on at least a portion of the surface thereof adapted to be in close proximity to the myocardium, and

conductor means for electrically interconnecting said energy processing means and said electrode means to conduct said electrical stimuli and said detected evoked potential therebetween.

10. The lead assembly of claim 9, wherein said iridium oxide coating has a thickness of at least 100 nanometers.

* * * * *

EXHIBIT G

US005318572A

United States Patent [19]

Helland et al.

[11] Patent Number: 5,318,572

[45] Date of Patent: Jun. 7, 1994

[54] **HIGH EFFICIENCY TISSUE STIMULATING AND SIGNAL SENSING ELECTRODE**

[75] Inventors: John R. Helland, Santa Clarita; Diane M. Muff, Granada Hills, both of Calif.

[73] Assignee: Siemens Pacesetter, Inc., Sylmar, Calif.

[21] Appl. No.: 892,463

[22] Filed: Jun. 2, 1992

[51] Int. Cl.[5] A61N 1/05

[52] U.S. Cl. 607/121; 607/122

[58] Field of Search 128/784, 785, 786, 642

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Primary Examiner—William E. Kamm
Assistant Examiner—Scott M. Getzow
Attorney, Agent, or Firm—Leslie S. Miller; Samuel M. Katz

[57] ABSTRACT

A pacing lead having a porous electrode of platinum-iridium with recessed areas or grooves formed into the surface. The grooves allow for acute electrode stabilization as a result of clot formation and endocardial tissue capture during insertion and immediate immobilization upon implant. At least one layer of a porous coating of 20–200 micron diameter spherical particles are deposited on the surface of the base electrode to obtain a porous macrostructure for promoting chronic tissue ingrowth. Additionally, a microstructure surface coating is applied to increase the active surface area and enhance electrical efficiency by lowering electrochemical polarization and increasing electrical capacitance.

24 Claims, 4 Drawing Sheets

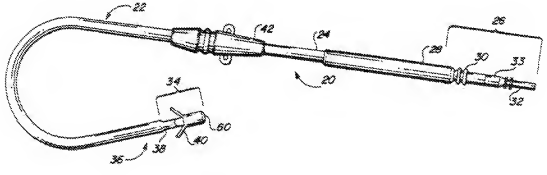


FIG. 1

FIG. 8

FIG. 7

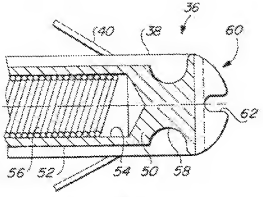


FIG. 2

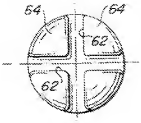


FIG. 3

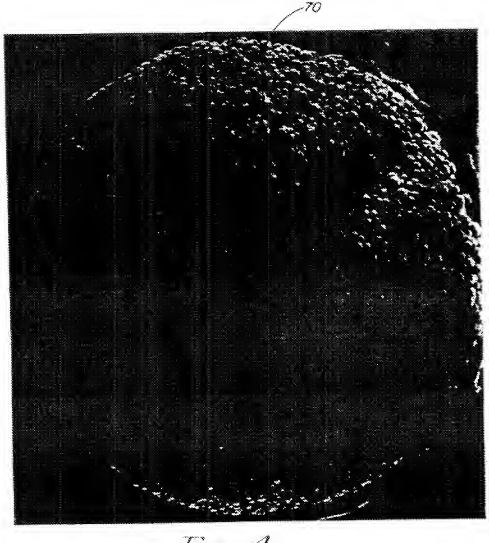
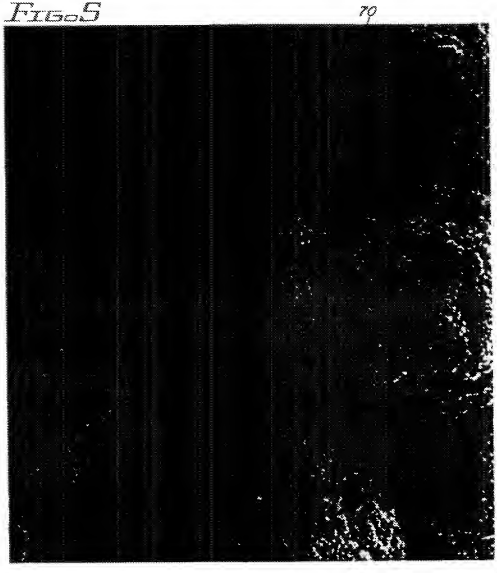


FIG. 4

FIG. 8



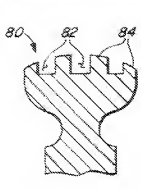


FIG. 9

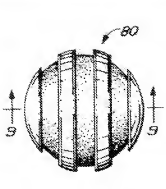


FIG. 10

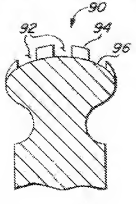
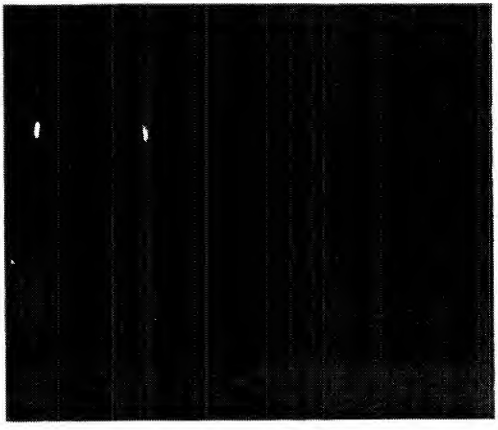


FIG. 11

FIG. 6



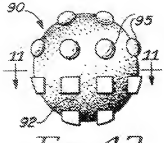


FIG. 12

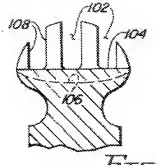


FIG. 13

FIG. 14

FIG. 15

HIGH EFFICIENCY TISSUE STIMULATING AND SIGNAL SENSING ELECTRODE

BACKGROUND OF THE INVENTION

This invention relates generally to an implantable pacing lead and more specifically to a pacing lead having a high efficiency tissue stimulating and signal sensing porous electrode for use with a cardiac pacemaker and a method for making the porous electrode.

For a cardiac pacemaker, implant lifetime is determined by the energy delivered per pulse. The pacemaker will have a longer life if the energy delivered per pulse is maintained at a minimum. Alternatively, the energy can also be used to provide for more features in the pacemaker. The design of an implantable pacing lead which is used with the pacemaker is influenced by the optimum signal for pacing stimulation. Physiologically, a cardiac pacemaker must be capable of generating a signal with a sufficient magnitude to depolarize the excitable cells of the endocardium. The electrode size, material, surface nature, and shape; the body tissue or electrolyte conductivity; and the distance separating the electrode and the excitable tissue, combine to determine the energy required of the pacemaker. Accordingly, the main factors to be considered with regard to the design of implantable pacing lead's electrode are: the size, surface nature, material and shape; the fixation of the electrode to the tissue; and the endocardial tissue reaction.

In selecting a pacemaker, the current drain, and therefore the implant lifetime, is determined by the impedance to pacing pulses. The pacemaker lead's electrode must be capable of delivering a pacing pulse with a pulse width generally in the range of 0.01–2.0 milliseconds and 0.5 to 10.0 volts to the tissue, and to also sense and transmit a QRS signal arising in the atria and ventricles of the heart to the pacemaker circuitry. Generally, the electrode-electrolyte system impedance is higher for sensing than for pacing. Pacing leads for pacing and sensing in the atrium, which can exhibit different stimulation and depolarization parameters than the ventricle, are also required.

The electrode-endocardial tissue system impedance characteristics may be understood in terms of an interface component and a spreading resistance component. The interface component occurs within a few microns of the surface of the electrode. The spreading resistance component depends predominantly on the tissue resistivity. Generally, the former reflects the charge transfer characteristics of the electrode-tissue interface influenced mostly by the surface area and material of the electrode, and the latter reflects the overall size and shape of the electrode; the surface nature of electrode; and the resistivity of the tissue.

The current drain of a pacemaker is determined by the impedance of the pacemaker circuitry, the nature of the electrode lead resistance, and the characteristics of the electrode tip interface with the electrolyte system. For a given pacemaker circuit and electrode lead design, the current drain is well defined. Thus, the nature of the electrode-endocardial tissue interface determines the overall current requirements of the system.

As an additional design factor, the most significant frequency of the pacing pulse is on the order of 1 KHz. At this frequency, the interface impedance is small and most of the impedance to the pacing pulses is due to the bulk or spreading impedance. This is determined by the shape and size of the electrode tip and is generally inversely related to the radius of the electrode tip.

The most significant frequency components of a signal to be sensed, i.e., the ventricular QRS, are in the bandwidth of 20–100 Hz. In this region, the interface impedance of the sensed signal becomes the most significant. The interface impedance is determined in large part by the microsurface area of the electrode tip and develops within a few microns of the surface. As described herein, the microsurface area of a porous electrode tip is the wettable surface, area which includes all of the exposed and interstitial porosity surfaces of the electrode tip.

As a final design consideration, it has been determined that the pacing or stimulation threshold is a reflection of the electrical energy required for a pulse to initiate a cardiac depolarization. The stimulation threshold typically rises for a period of a few weeks after the implant of a cardiac pacemaker generally as a result of an increase in the spacing between the electrode and the excitable tissue. The increase occurs due to the development of a fibrous capsule around the electrode tip. The thickness of the fibrous capsule is generally dependent upon the mechanical characteristics of the distal end of the lead (i.e., stiff or flexible), the geometry of the electrode tip; and the microstructure of the electrode tip, such as a porous electrode surface and the electrode material itself. In this regard, the environment of the endocardium must be considered. Specifically, the constant beating of the heart can cause the electrode to pound and rub against the endocardium, causing irritation and a significant subsequent inflammatory response, which ultimately results in healing, and the development of a fibrotic tissue capsule about the electrode tip. Also, a rough surface microstructure or one with sharp protrusions for the electrode will tend to be abrasive or traumatic on the abutting heart cells, also causing irritation, which also tends to cause the development of a thicker fibrotic capsule.

In view of the above characteristics of an electrode and its implantology issues for a cardiac pacemaker, it is clear that an electrode tip with a small geometric surface area (resulting in higher pacing impedance) will have a low current drain. However, in order to enhance sensing, the same electrode tip should have a large microsurface area and be of such a material to result in a low polarization and high capacitance which, in turn, results in a low sensing impedance and improved sensing. A cardiac pacemaker electrode tip that is constructed to be porous is therefore preferred in order to best satisfy these requirements.

In a pacemaker electrode, minimal tissue reaction is desired around the tip, but firm intimate attachment of the electrode to the tissue is essential to minimize any electrode movement relative to the abutting tissue. A porous electrode tip with macro tissue entrapping structure allows rapid fibrous tissue growth into a hollow area or cavities in the electrode tip to facilitate and enhance attachment of the electrode to the heart. A reduced lead dislodgement rate is also expected as a result of such tissue ingrowth. A further aspect of importance is selection of porosity size, which must be such as to accommodate economical construction techniques, overall dimensional tolerances, and tissue response constraints.

SUMMARY OF THE INVENTION

The pacing tip electrode of the preferred embodiment of the present invention is a five square millimeter platinum-iridium (90%/10%) porous electrode with recessed areas or slots in the shape of a cross formed into the surface. The grooves allow for acute electrode stabilization tissue ingrowth as a result of naturally occurring clot formation during insertion and helps result in immediate immobilization of the electrode upon implant. A porous coating of 20–80 micron diameter spherical platinum-iridium (90%/10%) particles are deposited on the surface of the base electrode to obtain a porous macrostructure for chronic tissue ingrowth and also for extending the active surface area. Preferably, the particles are deposited in a two-step process where the first layer of particles is made up of 40 to 80 micron spheroidal particles. The second layer is made up of 20 to 40 micron spheroidal particles. The result is a clumping of the particles producing a uniformly textured surface with randomized particle attachment. Chronic tissue ingrowth into this clumped, porous macrostructure enhances the electrode stabilization. Additionally, a microstructure surface coating is applied on these particles to increase the active surface area and enhance electrical efficiency by lowering polarization and increasing electrical capacitance. The macrostructure is preferably created by sintering the platinum-iridium particles to the platinum-iridium electrode tip. The microstructure coating is preferably created by reactive sputtering of titanium nitride onto the platinum-iridium particles.

DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a side plan view of a pacing lead according to the present invention.

FIG. 2 shows a cross-sectional view of the distal tip of the electrode of the lead shown in FIG. 1.

FIG. 3 shows an enlarged perspective view of the distal tip of the electrode of the lead shown in FIG. 1.

FIG. 4 shows an electron microscope photograph of the distal tip of FIG. 3, magnified by a factor of 50.

FIG. 5 shows an electron microscope photograph of the distal tip of FIG. 3, magnified by a factor of 500.

FIG. 6 shows an electron microscope photograph of the distal tip of FIG. 3, magnified by a factor 8000.

FIG. 7 illustrates a graphical depiction of the pacing threshold performance of an electrode constructed according to the present invention.

FIG. 8 graphically depicts the improved cardiac signal sensing for the electrode of the present invention.

FIG. 9 is a cross-sectional view of an alternative configuration for the distal tip of FIG. 1.

FIG. 10 is a plan view of the alternative tip configuration of FIG. 9.

FIG. 11 is a cross-sectional view of a second alternative configuration for the distal tip of FIG. 1.

FIG. 12 is a plan view of the alternative tip configuration of FIG. 11.

FIG. 13 is a cross-sectional view of an alternative configuration for the distal tip of FIGS. 2–3 or 9–12

FIGS. 14 and 15 schematically depict top and side views respectively of the microporous surface structure.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 shows a side plane view of a pacing lead 20 according to the present invention. The lead 20 is provided with an elongated lead body 22 which includes electrical conductors (not shown) covered with an insulation sheath 24. The insulation sheath is preferably fabricated of silicone rubber, polyurethane or other suitable biocompatible, biostable polymer. At a proximal end 26 of the pacing lead 20 is a connector assembly 28, which is provided with sealing rings 30 and which carries at least one electrical connector pin 32, and may also. The carry an anode terminal ring electrical connector 33. The connector assembly 28 is constructed using known techniques and is preferably fabricated of silicone rubber, polyurethane or other suitable polymer for insulating. Connector pin (or pins for bipolar or multipolar leads) 32 and connector 33 are preferably fabricated of stainless steel or other suitable conductive material.

At a distal end 34 of the pacing lead 20 is an electrode assembly 36 which is discussed in more detail below. Immediately behind the distal end of the electrode assembly 36 is a tine sheath 38 which includes a plurality of individual flexible tines 40. Tines 40 engage endocardial tissue and urge the electrode assembly 36 into contact with the endocardium, in a direction parallel to the axis of the electrode assembly 36. Tines 40 are more fully described in U.S. Pat. No. 3,902,501, issued to Citron et al., incorporated herein by reference. A fixation or lead anchoring sleeve 42, slidably mounted around lead body 22, serves to stabilize the pacing lead 20 at the site of venous insertion by means of suture ties about the sleeve and underlying fascia.

The electrode assembly 36 of FIG. 1 is shown in greater cross-sectional detail in FIG. 2. As illustrated, the electrode assembly 36 includes a conductive electrode 50 as well as the tine sheath 38 and the tines 40 thereof. The conductive electrode 50 is preferably a unitary construction including, at its proximal end, a cylindrical portion 52 defining an axial bore 54. A coil-wound conductor 56 of the lead body 22 of FIG. 1 is inserted into the axial bore 54 and affixed in electrical contact thereto, for example, by mechanical crimping or welding. Proceeding toward the distal end of the conductive electrode 50, the conductive electrode 50 includes a neck area 58 having a reduced diameter from the cylinder 52 which provides a recessed area into which an interior extending ridge of the tine sheath 38 is inserted to provide positive engagement of the tine sheath 38 with the conductive electrode 50. Finally, the conductive electrode 50 terminates at an electrode distal tip 60.

As illustrated in FIG. 2, the electrode distal tip 60 has a generally mushroom shape, such that the electrode distal tip 60 has a semi-hemispherical surface which is intended to provide electrical contact with the endocardial tissue. It should be appreciated that the electrode distal tip 60 may define a number of different profiles, from semi-hemispherical to essentially planar with rounded edges. As illustrated in FIG. 2 and more specifically in FIG. 3, the electrode distal tip 60 preferably includes at least one and preferably two or more recessed areas or grooves 62. The recessed areas or grooves 62 define generally pie-shaped segments shown in FIG. 3. These pie-shaped segments of the electrode distal tip 60 will be generally defined as the plateaus 64

within the specification, although it is recognized that the plateaus may be semi-hemispherical in shape, or utilize other configurations.

As discussed above in the background of the invention, the particular structure, i.e., the size, shape and porosity, of the electrode distal tip 60 is of particular importance to the functioning of the pacing lead 20, and the cardiac pacemaker system. The grooves 62 provide a means for capturing blood born cells during implant of the pacing lead. Specifically, the recessed areas or grooves 62 in the electrode distal tip 60 as illustrated herein, provide a capture site for blood cells and elements therein, including platelets, thrombin, red blood cells, and other elements, and the initiation of the formation of blood clotting upon insertion of the electrode assembly 36 into the vein of the recipient. As the lead body 22 of the pacing lead 20 is fed into the vein of the recipient, and the electrode assembly 36 proceeds to the heart, the platelets, thrombin, red blood cells, and other blood borne elements which are captured within the recessed areas or grooves 62 begin to form a thrombosis or blood clot. This blood clot, upon contact with the endocardial tissue, helps assist in affixing the electrode distal tip 60 to the endocardial tissue, to provide immediate stabilization of the electrode to endocardial tissue. The grooves also help to capture some amount of the soft, moldable endocardial tissue to also assist in immediately stabilizing the electrode tip.

It is anticipated that the grooves 62, while relatively shallow, will capture enough platelets, red blood cells, and other elements and endocardial tissue during the passage from the venous insertion point to the endocardium of the heart, to generally fill a majority of the recessed area. Accordingly, for a lead's electrode distal tip 60 having a diameter of between one and four millimeters, and a preferred diameter of two millimeters, the grooves 62 will have a depth in the range of between 0.1 and 0.5 millimeters and a width of between about 0.2 and 1.0 millimeters, and preferably, about 0.4 and 0.4 millimeters, respectively. Further, it is preferred that the edges of the grooves 62 be radiused in order to minimize tissue damages.

The electrode distal tip 60 is also treated to increase the porosity and active surface area, thereby enhancing the electrical efficiency by lowering the polarization and increasing capacitance. This texturizing treatment of the electrode distal tip 60 includes depositing generally spherical shaped small particles on the surface of the electrode distal tip 60, including all of the surfaces defining the recesses or grooves 62 as well as the plateaus 64. These generally spherical particles 70 are illustrated in the electron microscope photograph views shown in FIG. 4 and in FIG. 5 in greater detail.

Preferably, the conductive electrode 50 is made of a platinum-iridium composition. In the preferred embodiment, the platinum-iridium alloy has a composition of 90% platinum, 10% iridium by weight. The generally spherical particles 70 are preferably platinum/iridium (90%/100%) particles having a generally smooth surfaced spheroidal shape. It should be recognized however, that the electrode and the particles may be made of other suitable materials, such as titanium. The diameters of the spherical particles 70 should be in the range of between about 10 and 200 microns (0.01 mm to 0.20 mm), and preferably be in the range of between 20 and 80 microns (0.02 mm to 0.08 mm). Additionally, it is preferred that the spherical particles have a distribution of sizes spanning this range. Preferentially, two coatings of the spheroidal particles are applied to the base electrode. The first coating is preferred to be of particles in the range of 40–80 microns and the second coating 20–40 microns.

Upon affixation to the electrode distal tip 60, the generally spheroidal particles 70 will create a plurality of pore sites and interstitial porosity for chronic ingrowth of tissue. Preferably, by affixation of the spheroidal particles 70 having the preferred sizes and distribution of size, the interstitial porosity defined by the multiple layers of spheroidal particles 70 will have passageway dimensions which allow the passage of red blood cells (typically having a six-micron (0.006 mm) diameter) and other blood borne elements. By allowing the migration of red blood cells and other blood carried substances through the interstitial porosity, the events resulting in chronic tissue ingrowth are initiated.

The spheroidal particles 70 preferably have a generally smooth surface in order to minimize the amount of irritation of the endocardial tissue caused by the electrode distal tip 60 during the continuous beating of the heart. In addition to providing interstitial porosity for tissue ingrowth, the affixation of the spherical particles 70 also substantially increases the true surface areas of the electrode distal tip 60. Generally, by use of these spheroidal particles 70, the true surface area of the electrode distal tip 60 is increased by as much as a factor of five to twenty times.

Following affixation of the spherical particles 70 to the electrode distal tips 60, the electrode distal tip 60 and the particles 70 are treated with a surface coating means for increasing the active electrical surface area and enhancing the electrical efficiency by reducing the degree of electrochemical polarization and increasing the electrical capacitance of the electrode distal tip 60 during operation of the pacemaker system. Preferably, a nonmetallic material such as titanium nitride is used as the surface coating, as depicted in the electron microscope photograph of FIG. 6. In the electron microscope photograph of FIG. 6, a portion of the surface of the electrode distal tip 60 is enlarged by a factor of eight thousand. As may be appreciated from observing FIG. 6, the surface coating further increases the true surface area of the electrode distal tip 60 by a significant factor.

In addition to increasing the true surface area, the surface coating substantially enhances the electrical characteristics of the electrode distal tip 60. The surface coating increases the electrode's electrical capacitance and lowers the polarization developed at the electrode distal tip 60. It should also be noted that the surface coating on the spherical particles 70, while appearing to create relatively sharp edges thereon, does not result in irritation to the endocardial tissue because the relative size of the crystalline structure of the surface coating is substantially smaller than the heart's cells, the other cardiovascular tissue, and the blood elements which the coating will contact (i.e., red blood cells having an approximate diameter of six microns).

The surface coating is deposited in a manner such that the thicknesses of the surface coating attached to the spherical particles 70 is in a range of between one to thirty microns. While titanium nitride is the preferred surface coating material, other suitable nonmetallic coating materials, such as, for example, carbon, iridium oxide, and titanium oxide; and platinum oxide may also be applied as the surface coating of the electrode distal tip 60 following affixation of the spherical particles 70.

FIG. 7 is a graph depicting the generalized pacing threshold performance of an electrode constructed according to the present invention. In FIG. 7, the pacing threshold energy in microjoules is depicted on the Y-axis as a function of time, in weeks, along the X-axis, for two exemplary lead designs of the prior art and the lead 20 according to the present invention. In the graph, the average energy threshold is based upon voltage thresholds at various pulse duration and assumes pacing impedance remains generally constant. As depicted, the increase in the average energy requirement within the four to six weeks following implant is substantial for the pacing leads of the prior art. By comparison, the lead 20 of the present invention exhibits virtually no threshold increase, and remains relatively level at a lower average energy than either of the prior art leads. As may be appreciated, this will result in an increased threshold safety margin and/or a substantial increase in the useful life of the pacemaker system, given a fixed battery capacity since the required energy to stimulate the heart is low.

FIG. 8 graphically depicts the improved cardiac signal sensing capability of the electrode design of the present invention. In FIG. 8 the cardiac signal amplitude in millivolts is depicted on the Y-axis as a function of time (in weeks) on the X-axis, for the lead of the present invention and a lead according to the prior art. As depicted, the lead of the present invention maintains a relatively uniform high level for the cardiac signal amplitude, as compared to the prior lead which has both a lower initial level and a reduction over the course of the first two to three weeks. The primary difference reduced as a result of the significantly reduced polarization of the lead of the present invention, as discussed in greater detail below.

FIGS. 9 and 10 show a cross-sectional view and a top view of an alternative embodiment of an electrode distal tip electrode so for the electrode assembly 36 of FIG. 1. In FIGS. 9, 10, the electrode distal tip 80 includes a plurality of generally parallel grooves 82 defining therebetween generally parallel strip plateau sections 84. In the embodiment shown in FIG. 9, three grooves 82 are illustrated; however, it should be understood that a limited number of additional grooves may be incorporated. The number of the grooves 82 is limited by the size of the grooves appropriate for the capture of platelets, red blood cells, and other blood elements and tissue as described above, and the diameter of the electrode distal tip 80. In the preferred configuration, the diameter of the electrode distal tip 80 will be in the range of between one to four millimeters. Preferably, the diameter of the electrode distal tip 80 is approximately two millimeters.

FIGS. 11 and 12 show a cross-sectional view and a top plan view respectively of a second alternative embodiment of an electrode distal tip 90 for the electrode assembly 36 of FIG. 1. The embodiment of FIGS. 11 and 12 includes a plurality of intersecting grooves 92 which define therebetween generally square shaped plateaus 94. Alternatively the plateaus may be round in shape as shown by round plateau 95. As above, the grooves 92 are dimensioned so as to allow capture of platelets, red blood cells, and other blood elements during insertion of the lead 20 into the patient. In addition, as illustrated in FIG. 11, the grooves 92 are cut into the electrode distal tip 90 such that a base 96 of the grooves, when viewed in cross-section, defines a semi-hemispherical inner surface. Thus, in FIGS. 11 and 12, both the surfaces of the plateaus 94 and the base 96 of the grooves 92 define semi-hemispherical surfaces. This semi-hemispherical base surface configuration can also be incorporated into the designs illustrated in FIGS. 2 and 3, as well as in the design of FIGS. 9 and 10.

An additional alternative design configuration which may be incorporated into any of the three embodiments illustrated in FIGS. 2 and 3, 9 and 10, or 11 and 12, is illustrated in FIG. 13. In FIG. 13, the base of the grooves 102 is illustrated as either having a flat surface 104 or a concaved inner surface 106. Thus, in any of the electrode distal tip configurations of the present invention, it is contemplated that the base of the groove or grooves may define a concave base surface, a flat base surface or a semi-hemispherical base surface profile.

Additionally, while it has been illustrated in the figures that the walls 108 (FIG. 13) defining the grooves of the embodiments are illustrated as having generally flat surfaces which parallel the axis of the distal tip, it may be appreciated that the walls of the grooves may be generally angled with respect to the axis of the distal tip. In addition, the corners at the base and the peaks of the grooves for any of 30 the above described embodiments may be radiused to a radius of curvature of between about 0.001 mm and 0.5 mm, as opposed to having sharp edges. The grooves of any of the above embodiments may be formed by any of the methods selected from the group including stamping, milling, molding and electrochemical machining. The generally spherical particles 70 which are applied to the surfaces of the electrode distal tip 60 as discussed above with respect to FIG. 1 are also applied to the alternative embodiments of FIGS. 9 through 13, as is the titanium nitride or alternative surface coating treatment. The spherical particles 70 are preferably attached to the surfaces of the electrode distal tip by a process selected from the group of processes including sintering, laser fusion or welding, injection and molding casting. An example of one such attachment process is powder sintering, wherein a fractional percentage of the spherical particles are affixed in each of two to five successive steps.

Finally, the surface coating of titanium nitride or alternative material, is applied to the spherical particles 70 of the electrode distal tips 60 or any of the alternative embodiments of FIGS. 9 through 13 by a process selected from the group including sintering in an appropriate environment, vapor deposition, electroplating and sputtering.

The surface coating is illustrated in FIGS. 14 and 15 which schematically depict top and side views respectively of the microporous surface structure. FIG. 14 illustrates the generally pyramid-like shape of the microporous coating. In FIG. 15, a side or profile view of the microporous surface coating illustrates the triangular peaks of the coating, and more importantly the areas between the peaks of the coating which provides high surface porosity. With the foregoing construction, incorporating the microporous surface coating, the surface porosity or microporosity is in excess of fifty percent (50%), and preferably in the range of between sixty-five percent (65%) and seventy percent (70%).

A pacing lead having an electrode tip configured in accordance with the foregoing detailed description exhibits superior pacing performance. The primary reason for the superior performance is the reduction in polarization proximate the electrode tip. The "polarization voltage" for a pacing lead is herein defined to be

the voltage differential developed between the leading edge and the trailing edge of a reference electrical impulse. The reference electrical impulse is a 10 mA (milliampere), one millisecond, square wave, constant current pulse from a pulse generator. The polarization voltage (Pv) for a particular pacing lead is determined by subtracting the leading edge voltage (V1) from the trailing edge voltage (V2) of the reference electrical impulse (Pv=(V2−V1). During measurement of the polarization voltage, the electrode is immersed in a 0.15 molar sodium chloride (NaCl) solution, at a pH of 7, and temperature of 37° C.

As may be appreciated by those skilled in the art, the polarization voltage measured according to the above test will be influenced substantially by the size, shape, material, and surface nature of the electrode distal tip for a given pacing lead. Thus, for an electrode distal tip having a particular profile, and made of a particular material having a particular surface nature, the polarization voltages will be different for a 3 mm^2 tip and a 5 mm^2 tip. Conversely, two pacing leads having 5 mm^2 electrode tips will have characterizing polarization voltages which will depend on their particular profile, construction, material and surface nature. Generally the pacing lead electrode which has a lower polarization voltage for any given electrode design, or more simply the circumferential area, (cross-sectional area for a non-round tip) will be the more desirable pacing lead.

Accordingly, to further characterize pacing lead electrodes and more particularly the pacing lead of the present invention, a "polarization index" (PI) is herein defined. The polarization index is the polarization voltage Pv divided by the circumferential area CA (or cross-sectional area) of the electrode at its widest diameter. Thus, for a semi-spherical electrode having a diameter "d," the circumferential area CA is equal to $\pi(d/2)^2$, and the polarization index is given by the following formula:

$$PI=(V2-V1)/\pi(d/2)^2 \text{ or } PI=Pv/CA$$

The pacing leads of the present invention as disclosed in detail above have a polarization index PI which is less than 100 mV/mm^2. More particularly, in the preferred embodiments, the pacing leads of the present invention have a polarization index PI which is less than 50 mV/mm^2. A pacing lead having an electrode tip which combines a surface morphology allowing tissue ingrowth and very low polarization index levels is highly desirable in the field of implantable cardiac pacing leads.

It should be evident from the foregoing description that the present invention provides many advantages over pacing leads of the prior art. Although preferred embodiments are specifically illustrated and described herein, it will be appreciated that many modifications and variations of the present invention are possible in light of the above teaching to those skilled in the art. It is preferred, therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

What is claimed is:

1. An implantable pacing lead for use with a cardiac pacemaker comprising:

an electrical conductor having a proximal end and a distal end;

an insulative sheath covering said conductor;

an electrical connector coupled to said proximal end of said conductor; and

an electrode coupled to said distal end of said conductor, said electrode having an electrode tip geometry macrostructure defining at least two plateau sections separated by at least one recessed groove section, said plateau sections and said recessed groove section including surfaces having affixed thereto at least one layer of generally spheroidal conductive particles, said spheroidal particles coated with a layer of nonmetallic material selected from the group consisting of titanium nitride, iridium oxide, titanium oxide, platinum oxide, palladium oxide and activated forms of carbon, said layer of material having a surface morphology which results in a porosity of greater than about fifty percent.

2. The pacing lead of claim **1**, wherein said generally spherical conductive particles have diameters ranging from about 10–200 microns, said particles configured in at least one layer on said electrode surfaces to provide interstitial porosity for tissue ingrowth.

3. The pacing lead of claim **2**, wherein said electrode includes two recessed areas configured to intersect one another defining a cross shape.

4. The pacing lead of claim **2**, wherein said electrode includes at least two sets of multiple, parallel aligned, recessed areas, configured to have said multiple aligned recessed areas of said sets intersecting one another.

5. The pacing lead of claim **1**, wherein said spheroidal conductive particles are formed of a material selected from the group consisting of platinum, titanium, palladium, platinum-iridium, and carbon, said particles configured in at least one layer on said electrode surfaces to provide interstitial porosity for tissue ingrowth.

6. The pacing lead of claim **5**, wherein a majority of said interstitial porosity areas between said particles have a plurality of passage diameters greater than six microns to allow passage of blood cells.

7. The pacing lead of claim **5**, wherein said electrode includes at least two parallel aligned recessed areas defining at least three generally aligned plateau areas, and wherein the corners of said plateau areas each define an angle of at least sixty degrees.

8. The pacing lead of claim **5**, wherein said at least one recessed groove section has a profile defined by a depth of between 0.1 and 1.0 millimeters, a width of between about 0.2 and 1.5 millimeters, and each edge of said groove is radiused with a radius of curvature of between about 0.001 and 0.5 millimeters.

9. An implantable pacing lead for use with a cardiac pacemaker comprising:

an electrical conductor having a proximal end and a distal end;

an insulative sheath covering said conductor;

an electrical connector affixed to said proximal end of said conductor; and

an electrode assembly affixed to said distal end of said conductor, said electrode assembly including a porous electrode distal tip having a polarization index PI which is less than 100 mV/mm^2.

10. The implantable pacing lead of claim **9**, wherein said electrode distal tip further comprises:

at least one recessed area for capturing blood cells during insertion of said electrode assembly into a human recipient, and for promoting clot formation and endocardial tissue capture thereof to aid fixa-

tion of said electrode distal tip to endocardial tissue;

means for providing interstitial porosity and for increasing surface area of said electrode distal tip; and

coating means for enhancing the electrical characteristics of said electrode distal tip, for increasing the electrical capacitance, and for reducing electrochemical polarization at the electrode-endocardial tissue interface during pacing use.

11. The implantable pacing lead of claim 10, wherein said

at least one recessed area traverses said electrode distal tip, said at least one recessed area having a generally U-shaped profile defined by generally vertical walls and a base, said base having a transverse profile shape selected from the group consisting of semi-hemispherical, flat and concave.

12. The implantable pacing lead of claim 11, wherein said means for providing interstitial porosity and increasing surface area comprises:

a plurality of generally smooth surfaced spheroidal particles affixed to the surfaces of said electrode distal tip including said walls and base of said at least one recessed area.

13. The implantable pacing lead of claim 12, wherein said coating means comprises:

a surface coating applied to the surfaces of said distal tip electrode and said spheroidal particles thereon, said surface coating comprising a microscopically thin layer of a nonmetallic material selected from the group consisting of titanium nitride, titanium oxide, carbon, iridium oxide, and platinum oxide, said surface coating applied by a process selected from the group consisting of sintering, vapor deposition, electroplating and sputtering.

14. The implantable lead of claim 13, wherein said electrode distal tip further comprises:

at least two plateau areas separated by said at least one recessed area, said plateau areas having a generally semi-hemispherical profile.

15. The implantable pacing lead of claim 13, wherein said electrode distal tip includes two recessed areas configured to intersect one another, defining a cross-like shape.

16. The implantable pacing lead of claim 13, wherein said electrode distal tip includes at least two parallel aligned recessed areas defining at least three generally aligned plateau areas.

17. The implantable pacing lead of claim 13, wherein said electrode distal tip includes at least two sets of multiple, parallel aligned recessed areas, configured to have said multiple aligned recessed areas of said sets intersecting one another.

18. The implantable pacing lead of claim 13, wherein said at least one recessed area has a depth of between 0.1 and 1.0 millimeters and a width of between about 0.2 and 1.5 millimeters.

19. The implantable pacing lead of claim 13, wherein said plurality of generally smooth surfaced spheroidal particles have diameters distributed in the range of between about 10–200 microns, said particles formed of a material selected from the group consisting of platinum, platinum-iridium, titanium, palladium and carbon.

20. The implantable pacing lead of claim 13, wherein said electrode assembly has an electrode distal tip having a polarization index PI which is less than 50 mV/mm^2.

21. A method of forming an implantable pacing lead for use with a cardiac pacemaker comprising:

providing an electrical conductor having a proximal end and a distal end;

covering said conductor in an insulative sheath;

coupling an electrical connector to said proximal end of said conductor;

forming an electrode having an electrode tip geometry macrostructure defining at least two plateau sections separated by at least one recessed groove section;

affixing to said plateau sections and said recessed groove section a plurality of generally spherical conductive particles;

coating said particles with a layer of nonmetallic material selected from the group consisting of titanium nitride, palladium, platinum oxide, iridium oxide, and activated carbon; and

coupling said electrode to said distal end of said conductor.

22. The method of forming an implantable pacing lead of claim 21, wherein said coating of said particles is performed by a process selected from the group consisting of vapor deposition sintering, electroplating and electrode sputtering to a thickness of between 20–30 microns.

23. The method of forming the implantable pacing lead of claim 21, wherein said generally spherical conductive particles are affixed to said electrode distal tip by a process selected from the group consisting of powder sintering, laser fusion, welding, injection molding, and casting.

24. The method of claim 23, wherein said generally spheroidal conductive particles are affixed by one of said processes in a series of successive steps in which a portion of the particles are affixed by said process in each of said successive steps.

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